Summary of the 44th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING

Western Ecology Division
National Health and Environmental Effects Research Laboratory
U.S. Environmental Protection Agency
Corvallis, OR

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MONDAY, JULY 12, 2010

Welcome and Introductions

Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair

Dr. Gary Sayler, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC), called the meeting to order at 9:03 a.m., and welcomed the BOSC members to the 44th face-to-face meeting of the Executive Committee. He mentioned that the BOSC Executive Committee meets once each year at an EPA facility outside the Washington, DC, area, and this year Corvallis was selected. Dr. Sayler thanked Dr. Tom Fontaine, Director of the Western Ecology Division (WED) of the National Health and Environmental Effects Research Laboratory (NHEERL), for hosting the meeting.

Dr. Fontaine welcomed the BOSC members to Corvallis and encouraged participants to take a copy of the booklet on WED, which was available on the handouts table. The booklet contains descriptions of the research being conducted by WED. He stated that the meeting agenda includes two field tours during which some of the laboratory's research will be presented to the BOSC. He mentioned that representatives from the Government Accounting Office (GAO) were visiting WED and he would be dividing his time between the BOSC and GAO groups.

Dr. Sayler announced the presence of four new BOSC members—Drs. John Tharakan, Susan Cozzens, and Ken Olden, and Ms. Marie Zhuikov—and welcomed them to the Executive Committee. He pointed out that two of the BOSC members—Drs. Dennis Paustenbach and Katherine von Stackelberg were unable to attend the meeting, but Dr. von Stackelberg would be participating by telephone. Although he was not present, Dr. Sayler mentioned that Dr. Henry Falk was expected to arrive late (Dr. Falk, however, was unable to attend).

Review of April Teleconference Minutes

Dr. Sayler asked if there were any comments on the draft minutes for the April 1, 2010, conference call. When no comments were offered, Dr. Sayler called for a motion to approve the minutes. Dr. Barry Ryan moved to approve the minutes without any changes and Dr. Ken Demerjian seconded the motion. The minutes for the April teleconference were approved unanimously by the BOSC.

Overview of Agenda

Dr. Sayler gave a brief overview of the meeting agenda. The morning of Day 1 included the remarks from the Designated Federal Officer (DFO) for the BOSC, the remarks of the Assistant Administrator for

Research and Development (AA/ORD), an overview of ORD's chemical research realignment (Safer Products for a Sustainable World [SPSW]), presentation of the mid-cycle progress report for the Safe Pesticides/Safe Products (SP2) Research Program, and the mid-cycle progress report for the Human Health Risk Assessment (HHRA) Research Program. The afternoon of Day 1 began with a session on ecosystem informatics, which included presentations on computer science approaches to species modeling and mathematics of ecological dispersion. This session was followed by a 2-hour tour at the Corvallis facility. Day 2 began with a presentation of the ORD response to the BOSC Human Health Research Program Review Report. The morning also included an update from ORD and a report on the status of the BOSC and Science Advisory Board (SAB) liaison, as well as time for public comment. Also on the agenda was a review of the methods and procedures used to identify and prioritize research needs at the ORD Nanomaterial Case Study Workshop. The morning concluded with a discussion of future business. Following adjournment of the meeting, the BOSC Executive Committee met informally with GAO representatives and the afternoon concluded with a field study tour. Dr. Sayler asked if there were any questions or additions to the meeting agenda and there were none.

BOSC DFO Remarks

Mr. Greg Susanke, BOSC Designated Federal Officer, ORD, U.S. Environmental Protection Agency (EPA)

Mr. Susanke, the DFO for the BOSC Executive Committee, welcomed the BOSC members to the meeting and thanked them for their participation. He explained that the BOSC is a federal advisory committee that is subject to the requirements of the Federal Advisory Committee Act (FACA). Mr. Susanke reviewed the procedures that are required for all BOSC meetings. He stated that the BOSC provides independent, scientific peer review and advice to EPA's ORD, and it is his responsibility as the DFO to ensure compliance with all FACA rules.

In compliance with FACA requirements, all BOSC meetings are open to the public and time has been designated on the agenda for public comment. Mr. Susanke noted that although he received several requests for the agenda and materials, no requests for comment were received prior to the meeting. Time has been set aside on Tuesday's agenda at 10:15 a.m. (PDT) for public comment. He asked that comments be limited to 3 minutes each. An ORD contractor, Beverly Campbell from The Scientific Consulting Group (SCG), was present to take notes that capture the presentations and discussions. Following the meeting, she will prepare the meeting minutes, which will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the BOSC Chair.

As required by FACA, a notice of this meeting was published in the *Federal Register*. Mr. Susanke established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2010-0532. The agenda was made available to the public in the docket. Meeting materials are available upon request or they can be found on the BOSC internet site, http://www.epa.gov/osp/bosc. As the DFO, Mr. Susanke ensures that the Executive Committee members receive annual ethics training and complete confidential financial disclosure forms. He asked members to notify him immediately if any potential conflict of interest arose during the meeting deliberations, and he asked if any member had a potential conflict to declare. Regarding the session on the identification and prioritization of nanomaterials, Dr. Sayler said he would discuss his work with nanomaterials with the DFO to determine if a conflict of interest or lack of impartiality exists.

Mr. Susanke reminded the BOSC members and other participants to sign in at the registration desk if they had not done so already, and mentioned that Denise Hoffman from SCG was at the desk to help with any logistical needs.

Dr. Fred Hauchman said that he would be present for the entire meeting. He mentioned that Dr. Kevin Teichman, who usually attends the BOSC Executive Committee meetings, would be presenting the ORD

Update via videoconference. He added that Dr. Paul Anastas, the AA/ORD, also would be providing his remarks via videoconference. Dr. Hauchman stated that Dr. Anastas is keen on advancing the work of the BOSC, and really appreciates the work of the Board on behalf of ORD.

Dr. Sayler explained to the new Executive Committee members that the BOSC's role is to provide advice to ORD (not EPA). The BOSC is not the SAB; there are distinct differences and the members should keep these in mind. He asked if any of the new members would like to offer any comments.

Dr. Ken Olden said that it is important to him to know that ORD is listening and responding to the advice offered by the BOSC. He has been impressed with how responsive ORD has been to the BOSC in the past and he hoped that would continue in the future. Dr. Sayler agreed that ORD has been very responsive to the BOSC's comments, criticisms, and advice. The Board clearly has the opportunity to impact the long-term goals (LTGs) and directions of ORD's research. He noted that the work of the Decision Analysis Workgroup is a good example of how the BOSC is impacting ORD's programs.

Dr. Sayler stated that he hopes the BOSC can take on some additional tasks now that the Board is no longer conducting mid-cycle program reviews. This change has reduced the number of cyclical reviews and should free up some time to address other topics. Dr. Sayler mentioned that the meeting notebook contained a copy of Dr. Anastas' "ORD: The Path Forward" memorandum.

Dr. Sayler asked those joining the meeting via videoconference and telephone to identify themselves. When Dr. Anastas joined the meeting via videoconference, Dr. Sayler asked the BOSC members to introduce themselves. The Board members and other participants are included in the list of participants attached to this meeting summary.

AA/ORD Remarks

Dr. Paul Anastas, Assistant Administrator for Research and Development, ORD, EPA

Dr. Anastas greeted the BOSC members and offered a specific welcome to the new members of the Executive Committee. He apologized for not being able to attend the meeting in person, and explained that he had been spending a great deal of time in the Gulf and would be going down there later in the week. Dr. Anastas said he wanted to focus on some of the big issues being addressed by ORD since the last BOSC meeting. The major one is the response to the BP oil spill in the Gulf of Mexico. ORD has a diverse range of programs and capabilities and the Agency's response to the oil spill has tapped into every part of ORD. Dr. Anastas said he was very proud of ORD's efforts; the staff has been putting in long hours and a great deal of effort on this response. He noted that the BOSC would be hearing more on ORD's involvement in the oil spill response from Mr. Lek Kadeli on Tuesday. Dr. Anastas also mentioned some recent stories in the press that questioned the scientific integrity of the administration and EPA. He took exception to these stories and stressed the importance of confronting such stories quickly to dispel any misconceptions.

Referring to his "Path Forward" memo that was issued a few months ago, Dr. Anastas stated that one of his priority areas for ORD is to work closer with its program and regional partners; ORD is taking steps to engage these partners in time for the 2012 ORD research program planning. Another goal is to ensure that ORD's work is not fragmented and is conducted using a systems approach. ORD will be engaging in Integrated Transdisciplinary Research (ITR), which is defined as the process to develop sustainable solutions to environmental problems by engaging partners who transcend traditional scientific disciplines throughout each stage of the research process. Dr. Anastas also will be encouraging the development of sustainable technological innovations. He said he was meeting later that day with the EPA Administrator to discuss how to keep the Agency at the cutting edge of innovation and how to better communicate the impact of EPA's work. The Agency will need to make adjustments on how it aligns the budgetary structure to facilitate the flexibility needed to achieve these goals. ORD will be initiating a "seed grants" program that encourages high-risk proposals for catalyzing innovation and sustainable solutions. These

grants will allow investigators to prove the concept on a small scale, and those that are successful can apply for additional funding to continue their efforts.

ORD will build the goals of sustainability into its grant solicitations so that ORD is funding research that leads to sustainable solutions. ORD also is launching an impact initiative to improve the communication of how its research is impacting public health and the environment. Few of ORD's successes are widely known and that is impairing ORD's ability to have a greater impact. ORD is working to collect and translate the results of its research so that they can be communicated to stakeholders, the general public, and decision makers on Capitol Hill and elsewhere. He noted that ORD has not invested enough effort in this area in the past.

Dr. Anastas said that he had asked the Laboratory and Center Directors to dedicate time to the implementation and institutionalization of the "Path Forward" goals. A group known as the Delta Team has been formed to develop action plans to implement and institutionalize these goals. Dr. Anastas meets with this group daily and he expects the action plans to be completed by the end of July 2010.

Dr. Anastas asked if there were any questions from the BOSC members.

Dr. Olden said he was very impressed with Dr. Anastas' presentation, particularly the move to Integrated Transdisciplinary Research. He asked if ORD was considering a reorganization that would focus on problems rather than disciplines. Dr. Anastas replied that this exercise is not about a reorganization, rather it is a reorientation of ORD thinking. ITR will reorient the way ORD defines and implements approaches. Dr. Olden supported the increased emphasis on communicating the impact of ORD's research. He noted that the Agency's science is outstanding but often is poorly communicated.

Dr. Martin Philbert complimented Dr. Anastas' presentation and asked about ORD's role in integrating with other "sister" agencies working on the BP oil spill. Dr. Anastas responded that there are 18 different agencies involved in the response, and the Coast Guard has the lead. EPA is very involved and has been at the table for all the discussions. EPA will be meeting with the National Oceanic and Atmospheric Administration (NOAA) on July 19, 2010, to exchange data. Dr. Anastas pointed out that, as this moves from an emergency response to a recovery and restoration operation, access to scientific and technical input in real time will be required. EPA is working with other agencies to develop longer term plans to provide this support. The Agency is fully aware that the crisis does not end when the oil stops flowing, and ORD is preparing to meet the future challenges.

Dr. Philbert asked if there is a coordinated attempt to collect meaningful data while the oil is flowing. Once the flow of oil is stopped, these data will be used to assess the human health and ecological impacts over time. Dr. Anastas replied that all the data collected are being consolidated on a unified interagency Website. The agencies have coordinated on the type and breadth of data that need to be collected and they are sharing and centralizing these data. EPA is working with one of the health agencies on an initiative to make the critical linkage between environmental and health impacts. The Agency also is in discussions with natural resource agencies and NOAA regarding the follow-on efforts. He reminded the BOSC members that they will be hearing more on EPA's involvement in the oil spill response from Mr. Kadeli on Tuesday morning.

Dr. Sayler asked about the role the BOSC could play with respect to ITR. Can the BOSC offer ORD advice on how to implement it? Dr. Anastas responded that one particular area on which he is eager to obtain input from the BOSC is how to translate sustainability into the operational framework and then into research that affects the fundamental mission of the Agency.

Dr. Sayler asked if there were any more questions for Dr. Anastas, and when there were none, he thanked Dr. Anastas for his presentation and for taking the time to respond to the BOSC's questions.

Overview of ORD Chemical Research Realignment: Safer Products for a Sustainable World

Dr. Elaine Francis, National Program Director, Safe Pesticides/Safe Products Research Program, ORD, EPA

Dr. Elaine Francis mentioned that many of the colleagues with whom she worked to develop the framework for this realigned program were from Research Triangle Park, North Carolina, and Ada, Oklahoma, and they were participating by videoconference or telephone. She explained that today's presentation was merely an overview; more information on the program will be presented at the next BOSC Executive Committee meeting and ORD hopes to engage the BOSC in a dialogue about the program at that time.

A number of the research plans that are being incorporated into this new program are some of those that will be reporting to the BOSC at this meeting (e.g., SP2, Human Health). That is the primary reason that this briefing was included on today's agenda. She noted that ITR, which was described by Dr. Anastas, captures the essence of what ORD is trying to do with this new program. The research will be directed to finding sustainable solutions to environmental problems. This realignment is transforming what ORD does and how ORD does it in order to:

- ✧ Ensure that ORD's research addresses the most important environmental problems facing the Agency and the nation;
- ✧ Fully capitalize on ORD's ability to conduct ITR to solve these problems;
- ✧ Be solution-oriented so that ORD's work informs, enables, and empowers sustainable solutions to these problems;
- ✧ Work closely with ORD's partners to identify needs and conduct relevant research in a timely and responsive manner that meets actual, not perceived, partner needs, along with support for interpretation of complex data and conclusions; and
- ✧ Help ensure scientific integrity is the backbone of the Agency.

Dr. Francis used five words to describe ITR. It is **integrated** because it involves implementing systems thinking and integrative approaches to solve complex challenging problems. It is **transdisciplinary** because it involves the widest span of disciplines to bring different perspectives to the table. It is **innovative** because major challenges are not incremental problems and they require innovation. It is **catalytic** because of the need to act catalytically and spark further action among others. Finally, it is **visible** because communication is essential in the design, definition, conduct, transfer, and implementation of the work ORD does if it is to have an impact.

The attributes of an ITR process are that it is participatory (end-to-end), follows a critical path, and delivers the desired product. The results must be: relevant to decisions, compatible with existing policy-making processes, accessible to appropriate policy makers, timely, and in a usable format. In addition, policy makers must be receptive to the research results.

The vision for the new Safer Products for a Sustainable World (SPSW) Program is that EPA science will lead the sustainable development, use, and assessment of chemicals by providing a system of integrated decision support tools for more effective and efficient chemical management. Dr. Francis explained that for the SPSW Program, "chemicals" refers to intentionally produced/manufactured chemicals, particles, and materials and the products into which they are incorporated. This program is needed because EPA cannot efficiently or effectively assure the safety of chemicals with currently available approaches. This new program will develop innovative, systematic, and efficient approaches and tools needed to inform more sustainable solutions to the design and management of chemicals throughout their life cycles in a manner that reduces negative environmental and societal impacts while increasing economic value.

The SPSW Program will lead to smarter, more effective and efficient testing, assessment, and management of chemicals. It will focus on understanding the life cycle of chemicals and chemical mixtures, targeting those chemicals (or their byproducts) that are intentionally manufactured for commercial use. It will support research into alternative product formulations using green chemistry and green engineering principles, leading to the design of safer chemicals and products. It also will provide much higher throughput tools for the prioritization and biological screening of chemicals based on exposure and toxicity pathways. In addition, the program will: develop and apply innovative models for predicting exposures and dose and assessing risks for single and multiple chemicals, link predictive pathways with in-life effects using smarter testing and applying new principles for next-generation risk assessments, and improve technologies for managing risks and catalyzing solutions. The SPSW will include applications to human health and individual ecological species.

ORD is working to collaboratively develop and implement this innovative research program. ORD is integrating elements across ORD's current research portfolio into an ITR program, including resources from part or all of the following programs: Nanotechnology (all of this program), Computational Toxicology (all of this program), SP2 (part of this program), Endocrine Disruptors (all of this program), Human Health (part of this program), and Human Health Risk Assessment (part of this program). It will include both intramural and extramural research. Because the SPSW will focus on the Agency's highest-priority chemical needs, close collaboration across ORD and with the program and regional offices is required to develop and implement an innovative program that will serve to modernize the way chemicals are designed, evaluated, and managed. For this program, ORD will need to develop and enhance partnerships with industry, academia, nongovernmental organizations (NGOs), and agencies in the United States and other countries.

ORD hosted an initial problem formulation workshop with the program and regional office partners. The workshop was held on May 13, 2010, in Washington, DC. It provided the opportunity to work collaboratively during the problem formulation and to build a shared vision. Together, ORD and its partners identified key problem areas and began to develop a plan for working together to develop an ITR program. The program and regional offices were asked to nominate participants and 11 offices and Region 6 sent one or more representatives to the workshop. The program office and regional partners identified problem areas that need to be addressed.

A workshop with ORD senior scientists and managers was held on May 27, 2010. At this workshop, key scientific questions necessary to successfully solve the problem areas identified by ORD's partners in the program and regional offices were developed. The science questions continued SPSW problem formulation, and will lead to an ITR portfolio that develops intelligent testing strategies and evaluation approaches of inherent properties, and improves the relevance of assessment methods. Twelve ORD laboratories and centers participated in this workshop with senior scientists and managers.

A second workshop with the program and regional office partners was held on July 8, 2010, in Washington, DC. At this workshop, the problem formulation and scientific questions were verified. The strategy for engagement of stakeholders external to EPA was discussed, and ORD solicited review of the draft framework and input on opportunities for stakeholder engagement. The program offices that attended this workshop were the Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Water (OW), Office of Children's Health Protection (OCHP), Office of the Science Advisor (OSA), and Office of Environmental Information (OEI).

Dr. Francis provided a diagram of the SPSW framework. She explained that Research Area 1 (RA1) is Developing Integrated Evaluation Strategies, and the parameters to consider are inherency, exposure, hazard, and management. The work on RA1 feeds into RA2, which is Improving the Relevance of Assessment and Management Methods for Chemical Safety. This area looks at how one takes the information and applies it for a regulatory decision, site assessment, or other purpose. The work under

RA1 and RA2 feeds into the targeted research needs of the program and regional offices that will be addressed under RA3, which is Targeted Application of Integrated Evaluation, Assessment, and Management Methods. Dr. Francis noted that all work feeds back into improving the assessment and management methods.

The four levels for RA1 are:

- ✧ Level 1: Inherent Properties of Chemicals
- ✧ Level 2: Prioritization and Screening
- ✧ Level 3: Targeted Testing
- ✧ Level 4: Systems Models of Adverse Outcomes

The two levels for RA2 are:

- ✧ Level 1: Next Generation Risk Assessments
- ✧ Level 2: Risk Management Approaches

Dr. Francis then presented a schematic that illustrates the different levels in the research areas. Information on the chemical is gathered and decisions are made about its inherency, exposure, hazard, and management. Parameters for all levels are used in the integrated evaluation strategies. She pointed out that as the resource needs and level of effort increase, the residual uncertainty decreases.

Dr. Francis concluded her presentation by describing the next major steps for the SPSW. There will be a more detailed briefing for the BOSC at the October Executive Committee meeting. ORD will continue to work with program and regional partners to identify other opportunities and will develop a research portfolio. The SPSW Program is expected to be operational by October 2011.

Dr. Francis asked if there were any questions.

Referring to the schematic presented by Dr. Francis, Dr. Chuck Haas mentioned that the BOSC has been looking at various decision analysis techniques, including value of information (VOI). He suggested that ORD may want to consider moving modeling up earlier in the stream to help assess the needs downstream. He also mentioned the work on portfolio evaluation that had been undertaken by the BOSC. Dr. Francis responded that she was aware of these efforts and ORD is discussing how to incorporate them.

Dr. Philbert asked about the intended customers for the program's outputs. Dr. Francis replied that the program will develop tools for use by all the EPA program offices. These tools also can be used by others; for example, they can be used by other federal agencies to prioritize chemicals for testing and by industry for making decisions about safer chemicals. There is a broad audience of users. Dr. Philbert asked about the technical proficiency of these various audiences. The presentation did not mention communication and efforts to train the various users on how to use the tools. Dr. Francis responded that the users will have different levels of technical proficiency and the program will need to include efforts to ensure that those who need the tools know how to use them to address their needs.

Dr. Ryan complimented Dr. Francis on her presentation. He expressed some concern that the process might become unwieldy with so many different offices involved. He asked if this new program would subsume the SP2 Program and others or if these current programs would maintain their integrity and somehow report to the SPSW Program. Dr. Francis replied that the primary client of the new program is OCSPP and this office is working closely with ORD, along with Region 6 (the lead region for this area), to develop the program. The SPSW Program represents a new way of doing business and it is expected that the EPA program offices involved with the program will communicate it to other partners and catalyze their involvement. With respect to the SP2 Program, the entire program will become part of the

SPSW Program and the SP2 Program will no longer exist. This also is true for the Nanotechnology, Computational Toxicology, and Endocrine Disruptors Programs.

Dr. Olden noted that there was no mention of susceptibility studies as a function of exposure or risk in the presentation. He asked Dr. Francis to comment on this. Dr. Francis explained that the presentation was a brief overview. Life styles, genetics, age, and other issues are addressed in the scientific questions but she did not go into that level of detail. Dr. Olden asked how the program planned to engage social and behavioral scientists; he noted that they are important in reaching communities. He suggested that they should be involved in providing advice on translation. Dr. Francis replied that there are not many social and behavioral scientists in ORD so the program probably will seek this expertise through extramural grants; however, ORD wants to engage them in the design process so that they can provide valuable advice, particularly on how to get the tools into a format that users can apply.

Dr. Sayler thanked Dr. Francis for her presentation and said that the Board is looking forward to the discussion of this program in October.

Mid-Cycle Progress Report for the Safe Pesticides/Safe Products Research Program

Dr. Elaine Francis, National Program Director (NPD), Safe Pesticides/Safe Products Research Program, ORD

Dr. Francis provided some background and history on the SP2 Research Program. The program is providing OCSPP with test methods for use in developing testing guidelines by which chemical and agricultural industries conduct and submit data to assess potential human and ecological risks for more than 25 years; conducting research on underlying science to assist in interpretation of data from industry-submitted studies; and responding to OCSPP's requests on specific shorter term research needs by providing results on the effects, exposures, risk assessment, and/or risk management of chemicals or classes that are of immediate concern to the program office. The biotechnology research program was initiated in FY 2002.

The SP2 Research Program has three LTGs:

- **LTG 1**—(1) prioritization of testing requirements, (2) enhanced interpretation of data to improve human health and ecological risk assessments, and (3) decision making regarding specific individual or classes of pesticides and toxic substances that are of high priority.
- **LTG 2**—probabilistic risk assessments to protect natural populations of birds, fish, other wildlife, and non-target plants.
- **LTG 3**—decision making related to products of biotechnology.

The BOSC program review of the SP2 Research Program took place February 7-9, 2007, in Research Triangle Park, North Carolina. Dr. Anna Harding chaired the BOSC Subcommittee, and Dr. Barry Ryan served as the Vice-Chair. Seven additional experts completed the Subcommittee. The program was assessed in terms of relevance, structure, performance, quality, scientific leadership, and coordination and communication. The final report for this program review was transmitted to ORD on July 23, 2007, and ORD submitted a response to the BOSC's review on January 12, 2008.

The BOSC thought the SP2 Research Program was a very successful program. Its quality was high, which was supported by strong evidence of relatively high publication and citation rates in high-visibility journals of significant scientific reputation, by the immediacy with which the papers were recognized, and by the ultimate use of the research by the Agency. The program's goals were well articulated and its framework was well thought out, logical, and laid out in a reasonable and integrated manner. The relevance of the program to the Agency's mission was clear and apparent, and it was filling a unique niche. The program appeared to be making solid progress on achievement of all three LTGs and in

meeting intermediate range milestones. The scientific leadership of the program was strong. It included a community of highly trained and energized researchers, many of whom are leaders in their field. The strategies for coordination and communication were very good and there was vertical and horizontal coordination and communication within and outside EPA. There was extensive interaction with the Office of Prevention, Pesticides, and Toxic Substances (OPPTS, which now is OCSPP) demonstrated at the review, and good communication with Science To Achieve Results (STAR) grantees and other researchers at STAR meetings as well as professional meetings.

The BOSC assigned a rating of exceeds expectations for LTG 1, and a rating of meets expectations for LTGs 2 and 3. The 22 recommendations in the BOSC report were organized under the following nine categories:

- ✧ Clarify Annual Performance Goals (APGs) and Annual Performance Measures (APMs) (4 recommendations)
- ✧ Strengthen Exposure Research (2 recommendations)
- ✧ Clarify Criteria for Decisions Made (2 recommendations)
- ✧ Improve Ecological Modeling Research (3 recommendations)
- ✧ Improve Biotechnology Research (2 recommendations)
- ✧ Enhance Cross-Disciplinary Approaches, Collaborations, and Communications (5 recommendations)
- ✧ Continue Current Practices (2 recommendations)
- ✧ Nanotechnology Research (1 recommendation)
- ✧ Additional Information for Further Reviews (1 recommendation)

The mid-cycle progress report builds on the original comments and recommendations made by the BOSC at the program review. It captures the original comments, ORD's 2008 response, and the anticipated actions and timeline for implementation. The progress report also describes the program's progress in addressing each comment and recommendation and identifies further actions and the timeline for those actions. The report includes a table that summarizes all of this information.

Four of the original recommendations fell under the topic Clarify APGs and APMs. These included: Recommendation 2–*Retain flexibility of research structure to emerging science and clarify the APGs/APMs*; Recommendation 3–*Clarify the relationship between APGs and APMs, and ensure consistency between the text and the research*; Recommendation 7–*Emphasize the need for transparent validation/verification of research products*; and Recommendation 14–*Revise APGs to ensure there are sufficient resources to reach goals*. In its 2008 response, ORD noted that improving APGs and APMs is an ongoing process. ORD indicated that the next update of the MYP will: clarify the generic relationship between APGs and APMs, reflect new metrics for APGs/APMs agreed upon with OMB, and reflect improvements in clarity and consistency in APGs/APMs. In addition, ORD will reword the specifically identified APG to clarify the distinction that ORD develops methods/models, while the validation is conducted by an independent group of experts. The updated MYPs will continue to have APGs/APMs that are achievable given the program's available resources.

The SP2 Program has made progress in addressing these recommendations and implementing the response actions. Revised MYP guidance was issued in 2008, which provides more details concerning ORD's approach to capturing the program's work through APGs and APMs. The APMs/APGs now are Web-based to allow more flexibility and to facilitate the evolving nature of both the research and the efforts to capture and communicate the results. ORD's National Homeland Security Research Center (NHSRC) initiated a 1-year pilot in October 2009 for which the APMs include explicit mention of

partner(s) and delivery dates as well as a partner "feedback loop." The results of this pilot will be evaluated later this year to inform ORD's guidance on APGs and APMs.

The SP2 Research Program MYP has not been revised since the program review because the program is undergoing a merger with other research programs to develop the SPSW Research Program. The BOSC's recommendations will be considered in this new program, which is expected to be operational in FY 2012.

Two of the BOSC's recommendations fell under the topic of Strengthen Exposure Research. These included: Recommendation 4–*Greater emphasis is needed on exposure-related research* and Recommendation 6–*Perform an integrated evaluation of human health to provide advice on program balance, especially with respect to exposure*. ORD's 2008 response was that it would shift FTEs for exposure research into the SP2 Program. ORD was developing an Implementation Plan for exposure research that was being integrated with the effects research; it was expected to be completed in 2008. ORD's response also indicated that the next update of the MYP would incorporate the strengthened exposure research, and include an approach that provides stronger evidence of linkages to exposure research conducted through other ORD programs, and that is relevant to OPPTS' needs, for improved communication.

With regard to these recommendations and responding actions, ORD shifted exposure research FTEs into the SP2 Research Program. ORD also is developing integrated exposure-effects spatially explicit ecological risk assessment models. A partners' workshop on models development will be held July 13-15 with OCSPP. A draft research plan should be prepared by September 2010, and a final research plan by January 2011.

Integrated multidisciplinary research is being conducted to address the Agency's highest priorities related to perfluorinated compounds (PFCs). The exposure research is integrated with that of effects and risk management, and it is informing Agency decisions. The exposure research strategy workshop was held in March 2010, and a workshop report was completed in July 2010. The draft research plan is expected to be completed by August 2010, and finalized by December 2010. Since the BOSC program review, there have been two international PFCs symposia—one in June 2008, and the other in June 2010. A special journal issue was published in 2009 from the 2008 workshop, and two special journal issues from the 2010 workshop will be published late 2010 or early 2011.

The SPSW Research Program is being developed with resources from parts or all of the SP2, EDCs, Computational Toxicology, Human Health, HHRA, and Nanotechnology Research Programs. This new program will improve the leveraging of resources, research planning, and the implementation and communication of ORD's research products. The BOSC's recommendations will be considered in under that new program, which is expected to be operational in FY 2012.

The two recommendations under the topic of Clarify Criteria were: Recommendation 8–*Clarify criteria used to select new compounds for study and expand the current list*, and Recommendation 16–*Describe criteria for prioritization of future work should additional resources become available*. ORD's 2008 response was that the next update of the MYP will: (1) clarify how OPPTS identifies and prioritizes those research elements needed in the shorter term, based on impending regulatory decisions or data gaps; (2) provide greater detail on the prioritization process used to accelerate research previously identified as high priority, should additional resources become available; and (3) provide stronger descriptions of potential new research directions based on discussions with OPPTS senior managers.

The ORD transformation and the development of the SPSW Research Program will provide ORD a more rigorous and reiterative process to work with program and regional office partners as well as external stakeholders, across all of its laboratories and centers. Prioritization of the science questions will be included from problem formulation through product delivery. The leveraging and prioritization of

resources and research efforts as well as communication of research products will be improved. As the SPSW Program develops, the BOSC's recommendations will be considered. Dr. Francis reminded the BOSC members that the SP2 MYP had not been updated because of development of the SPSW Program.

The three recommendations under the topic Improve Ecological Risk Assessment Approaches were: Recommendation 9–*Begin movement towards an ecosystems approach that fully assesses population and community risks*; Recommendation 10–*Further develop mathematical foundations that underpin current efforts*; and Recommendation 11–*Pursue collaborations and extend development to advance high performance computing methods for probabilistic risk assessment*. ORD's response in 2008 indicated that the shift of exposure FTEs into the program will result in moving toward an integrated (exposure-effects), spatially explicit risk assessment program for targeted population and communities that will expand their utility. ORD indicated that these recommendations would be addressed through the development of the exposure Implementation Plan and would be incorporated into the next iteration of the MYP. At the time of the response, efforts were ongoing to develop Web-based applications of ORD products and to seek research partners to help provide tools that ORD's clients can readily access.

Since the BOSC review, exposure FTEs have been shifted into the SP2 Research Program and integrated exposure-effects ecological risk assessment tools are being developed. The program is working with EPA's OEI to incorporate state-of-the-science high performance computing and visualization techniques. In addition, the program is working with the National Center for Computational Toxicology (NCCT) on its research to build a Virtual Tissues knowledgebase and a cell-based tissue simulator focused on the Virtual Liver (v-Liver™) and the Virtual Embryo (v-Embryo™). The knowledgebase will be a free publicly available tool that synthesizes published experimental observations on the effects of chemicals on the potential toxicological processes. The cell-based tissue simulator will simulate chemical-induced effects in the liver and the embryo using three interconnected systems micro-circulation, cell and molecular response, and tissue response.

The two BOSC recommendations under the topic Improve LTG 3–Biotechnology were: Recommendation 1–*Include approach to address issues of mitigation potential on gene transfer, effects on non-target organisms, and targeted species resistance*; and Recommendation 12–*Broaden the scope of the program to include additional topics identified by the reviewers*. ORD's 2008 response indicated the following: (1) field-scale protocols for non-target species effects were being developed/applied; (2) a workshop on Pollen Mediated Gene Flow was held in 2007; (3) a report on testing and evaluation of resistance management models that track development of resistance in genetically modified crops will be released in 2009; (4) limitations in resources prevent expansion into other areas; and (5) the program is continually seeking partners (e.g., in 2007, a joint Request for Applications [RFA] on food allergenicity was issued with the National Institute of Allergy and Infectious Diseases [NIAID]).

Since the BOSC review, budget constraints have resulted in resources either being eliminated or realigned to address higher priority Agency issues. An integrated exposure-effects ecological assessment research program is being developed and the program has leveraged resources to characterize the effects of chemical and non-chemical environmental stressors on plant populations. In addition, the SP2 Program is supporting ORD's new Biofuels Research Program. In the area of food allergenicity, the program issued a joint RFA with NIAID, the Food Allergy Project, and the Food Allergy and Anaphylaxis Network, which collectively awarded 16 grants (4 by EPA) that are being tracked. This research will be completed in late 2010/early 2011. A joint workshop, held in 2008, led to publication of a paper on the state-of-the-science and remaining research needs as well as a session at the 2009 Society of Toxicology meeting. EPA issued a new RFA in 2009, and the awards are pending. It is anticipated that there will be four awards, each with a period of 3 years. The results from past activities have been published or submitted for publication and are either in press, accepted, or in review. No further biotechnology research will be conducted.

There were five BOSC recommendations under the topic Enhance Cross-Disciplinary Approaches, Collaborations, and Communications. These were: Recommendation 5–*Mechanisms to improve communications between groups doing research on LTGs 1 and 2 are recommended*; Recommendation 13–*Maintain and build upon existing cross-disciplinary and cross-organizational collaborations*; Recommendation 17–*Grow and collaborate in the areas of statistical analyses, bioinformatics, theoretical mathematical model building, and probabilistic risk assessments*; Recommendation 21–*Emphasize communication with other federal laboratories*; and Recommendation 22–*Develop a more focused communications program to regions and other program offices*. ORD's 2008 response indicated that the update of the MYP will provide greater detail on the extensive ongoing collaborations with scientists in other federal agencies and research organizations. Significant collaborations were occurring in the area of bioinformatics with STAR-funded Environmental Bioinformatics Research Centers and the program would continue to seek new collaborations. Four senior bioinformaticians and systems biologists had been hired. The program had initiated efforts to improve coordination and communications. An ORD-OPPTS (and other program/regional offices) senior managers' meeting was to be held in 2008.

Since the BOSC review, the SP2 Research Program has strengthened its cross-organizational and cross-disciplinary partnerships across the ORD laboratories/centers, within EPA, with other federal agencies, and with states. Examples of these partnerships are provided in the progress report. ORD implemented actions to enhance efforts in bioinformatics and systems biology. ORD awarded two new STAR Centers in the form of cooperative agreements to allow for greater interactions between EPA and academic scientists (in 2008 and 2009). The program is using community of practice (CoP) approaches to communicate and receive input from scientists across sectors from around the world. In addition, NHEERL has established a new Integrated Systems Toxicology Division and has advertised for a senior-level Director. ORD and OCSPP senior scientists and managers met in November 2009, to identify and prioritize research needs. Addressing these needs will be advanced further through the development and implementation of the SPSW Research Program, which is expected to be operational in 2012.

The two recommendations under the topic Continue Current Practices included: Recommendation 19–*The peer-review process should be continued*, and Recommendation 20–*Continue to reward scientific excellence and minimize administrative burdens*. ORD's 2008 response indicated that the program continually follows existing guidance and policies to ensure that programs and products are appropriately peer reviewed. In addition, ORD uses all available mechanisms to reward and retain its scientists and to recruit new ones.

The progress report states that the 2006 *Peer Review Handbook, 3rd Edition* still governs ORD's approach to peer review, and that approach is used by the program. Efforts are ongoing to use all mechanisms available to reward and retain the SP2 Research Program scientists and managers and to recruit new ones when warranted. The program has brought on board postdoctoral fellows, graduate students, student interns, and Association of Schools of Public Health (ASPH) fellows. In addition, some of the senior scientists hired by ORD through the Title 42 authority spend some of their time on SP2 issues. Researchers and managers continue to receive rewards for their efforts devoted to the SP2 Research Program through the EPA and ORD awards processes and the Science and Technology Achievement Awards.

The recommendation that falls under the topic Nanotechnology was Recommendation 15–*More rapidly develop a research program in nanotechnology and encourage other international organizations*. In 2008, ORD responded that a Nanomaterial Research Strategy (NRS) had been developed. The response also indicated that EPA was collaborating with other federal agencies to develop complementary research portfolios and with academia and industry to fill knowledge gaps. In addition, the program was collaborating internationally and was part of the Organisation for Economic Co-operation and Development's (OECD) efforts.

Since the BOSC review, ORD has implemented the NRS (in 2009) and added an intramural component to the program. ORD's nanotechnology program complements those of other federal agencies, and is collaborating with the research of other government agencies through the OECD. In addition, joint and coordinated RFAs with other federal agencies, the United Kingdom, and the European Commission have been issued under the STAR Program.

Recommendation 18–*Map service awards (as well as peer-reviewed papers) to individual program elements to better designate high quality products* was the only recommendation under the topic Additional Information for Reviews. In 2008, ORD responded that it will continue to include service awards in staff members' biosketches for all reviews and in integrated tabular format, where possible. Guidance regarding the value-added of collecting and presenting more detailed information for BOSC reviews was being discussed by ORD and the BOSC at the time of the response.

The BOSC Executive Committee meeting that took place at the time of the response did not result in any agreement regarding the tracking and reporting of awards for ORD's program reviews. The subject of demonstrating the high quality of the program's research remains a priority. The current plan is to demonstrate the perceived quality of the research team and its technical and scientific products by providing partner/client testimonials and interviews, and by using bibliometric analysis. ORD is exploring new bibliometric approaches to measure not only quality of the work but also performance of the various research programs. These new approaches will be implemented in 2011. ORD will continue to engage the BOSC Executive Committee in developing appropriate bibliometric measures to be used in the program reviews.

In closing her presentation, Dr. Francis expressed the Agency's gratitude to the BOSC Subcommittee that conducted the review and provided thoughtful comments and recommendations. She also thanked the BOSC Executive Committee for the opportunity to present the progress that had been achieved since that review. Many comments and recommendations have been addressed. For example, there is improved integration of exposure research, expanded collaborations with partners, and improved communication of research products. In addition, the SP2 Program has continued with commendable good practices. The other comments and recommendations from the review will be taken into consideration as the new SPSW Research Program develops. Dr. Francis said that she looks forward to continued interactions with the BOSC Executive Committee.

Dr. Sayler thanked Dr. Francis for her presentation and asked if the BOSC members had any questions. Dr. Olden stated that in the section on metrics for measuring impact, bibliometrics was mentioned; however, the ultimate metric is the impact on public health. Is ORD making an effort to gather information on the impact of the program on public health? Dr. Francis replied that ORD has been grappling with how to measure the impact of its programs. ORD currently does not have the tools to do so. EPA has asked the National Academies for its input on effective measures and ORD has been working with other agencies on this as well. Most of the measures are anecdotal rather than quantitative. Dr. Francis said that ORD would welcome input from the BOSC on effective metrics for measuring the impact of ORD research programs. Dr. Olden also asked if ORD had used the Agency's Title 42 authority to bring in scientific leadership from outside EPA. Dr. Francis responded that most of the experts who have been hired under the Title 42 authority are from outside the Agency.

Dr. Philbert asked if the $8 million for nanotechnology research was for both intramural and extramural research. Dr. Francis responded that both were included, and she added that the FY 2011 budget is $20 million. Dr. Philbert inquired about the split between the two, and Dr. Francis replied that approximately $7 million is for extramural research and the remainder is for intramural research, personnel, and other expenses. Dr. Philbert then asked about the fate of the SP2 Program given the new SPSW Program. Will the work be carried on under that new program? Dr. Francis explained that some of the SP2 research would be continued under the SPSW, in particular, the spatially explicit modeling. The work dealing with population level research would be carried out under another program. In response to Dr. Francis'

request for input from the BOSC on appropriate metrics, Dr. Philbert mentioned that the BOSC had recommended that ORD look at how the research program and its products affect legislation, rulemaking, policy, and other outputs beyond publication in the scientific literature.

Dr. Olden asked if the program was allowed to do public education. He stressed the need to educate the public about the safety of new technologies, genetically modified plants, and many other issues. Dr. Francis answered that she was not aware of any restrictions with respect to educating the public; however, that is more the role of the program office, which has a division that deals with outreach and education. Dr. Olden noted that ORD plays an important role in translating research so that it has an impact on public health, and public education is an essential component of that effort. Those who develop the research also should plan for public education at the outset of the program. Dr. Sayler pointed out that there are limited funds within ORD to perform this important role.

Dr. Ryan, who served on the BOSC Subcommittee that conducted the program review of the SP2 Research Program, said that he thought the mid-cycle progress report addressed all of the questions and issues that were raised by the Subcommittee.

Mid-Cycle Progress Report for the Human Health Risk Assessment Research Program

Ms. Becki Clark, Acting Director, National Center for Environmental Assessment (NCEA)

Ms. Becki Clark explained that she was serving as the Acting Director of NCEA while Dr. Peter Preuss is on a temporary assignment. She introduced the other EPA staff members who were joining her on the videoconference from Washington, DC. Ms. Clark said that she moved to NCEA in 2007, just before the BOSC conducted its review of the Human Health Risk Assessment (HHRA) Research Program. Since that review, Ms. Clark has seen substantial progress within NCEA on addressing the issues raised by the BOSC; she added that the BOSC review was very helpful in moving the HHRA Program forward.

The HHRA Program is managed by NCEA, which is the entity within ORD that develops human health assessments, conducts research on human health risk assessment methods, and develops guidance for assessments. NCEA occupies a critical position in ORD between the researchers in other ORD components that are generating new findings and data and the regulators in the EPA program offices and regions who must make regulatory, enforcement, and remedial action decisions.

The three LTGs of the HHRA Research Program are:

- **LTG 1: Integrated Risk Information System (IRIS) and other priority health hazard assessments—**Agency, state, and local risk assessors use the state-of-the-science health hazard assessment information provided on priority substances in their decisions and actions to protect human health from risks posed by environmental pollutants.
- **LTG 2: State-of-the-science risk assessment models, methods, and guidance—**EPA programs, states, and other risk assessors use the risk assessment models, methods, and guidance provided to enhance, through the incorporation of contemporary scientific advances, the quality and objectivity of their assessments and decision-making on environmental health risks.
- **LTG 3: Integrated Science Assessments (ISAs)—**As mandated in the Clean Air Act, the ambient air criteria pollutants are reviewed and ISAs revised to reflect the best available scientific information on identifiable effects on public health and the environment from exposure to the pollutant, and this information is used by the EPA Office of Air and Radiation in its review and promulgation of the National Ambient Air Quality Standards (NAAQS) to protect public health with an adequate margin of safety.

These LTGs are identified in the HHRA Multi-Year Plan (MYP) that was last updated in August 2007; Ms. Clark noted that the MYP will be updated soon.

The activities for LTG 1 (IRIS and other priority health hazard assessments) include:

- ✧ Developing human health assessments (e.g., tetrachloroethylene, methyl tertiary butyl ether, ethylene oxide, trichloroethylene [TCE], acrylamide, formaldehyde, asbestos, and 72 others).
- ✧ Preparing Provisional Peer Reviewed Toxicity Values (PPRTVs) for EPA's waste site clean-up program (Superfund): PPRTVs for 69 chemicals were completed in FY 2009.
- ✧ Developing Incidence Response Assessments (e.g., Hurricane Katrina health impact assessment of debris incineration, impacts assessment of dust from collapse of the World Trade Center, Gulf Oil Spill).

The activities for LTG 2 (state-of-the-science risk assessment models, methods, and guidance) include:

- ✧ Uncertainty analysis
- ✧ Identification of possible modes of action
- ✧ Physiologically-based pharmacokinetics (PBPK) modeling
- ✧ Approaches to quantification
- ✧ Approaches for assessing risk of environmental exposures to susceptible populations
- ✧ Approaches for cumulative risk assessment.

Under LTG 3, the program produces ISAs that provide the scientific bases for EPA's air quality decision-making. The activities include:

- ✧ Ozone—completed February 2006; underway – first draft November 2010
- ✧ Lead—completed September 2006; Lead ISA Information Call-in – 2010
- ✧ Particulate Matter—Completed 2009
- ✧ Nitrogen Oxides—ISA and Health and Environmental Criteria – both final in 2008
- ✧ Sulfur dioxide—ISA and Health and Environmental Criteria – both final in 2008
- ✧ Carbon Monoxide—Completed 2010.

In the report on the 2007 review of the HHRA Research Program, the BOSC provided positive feedback on all aspects of the program: relevance, structure, quality, performance, leadership, collaboration, and outcomes. LTGs 1 and 3 received a rating of meets expectations from the BOSC, and LTG 2 was assigned a rating of exceeds expectations. The BOSC offered 10 specific recommendations that fell into three major areas: (1) planning and implementation, (2) customer needs, and (3) coordination and communication.

To address Recommendation 1: *Assess program needs in order to increase production of IRIS and PPRTV Assessments* and Recommendation 5: *Establish goals for increasing the number of IRIS assessments to meet client needs*, the program implemented a new, streamlined IRIS process in May 2009, and the HHRA Research Program has quickly demonstrated progress. The IRIS logistics team was created to centralize all aspects of the administrative support for IRIS, enhance efficiency, and relieve the administrative burdens from the scientific staff. In addition, the program meets with the client office to better understand its assessment needs. Also, to address these two recommendations, the HHRA Research Program streamlined the production of PPRTVs and in FY 2009, 69 PPRTV assessments were added to the database. New program metrics were negotiated with the Office of Management and Budget (OMB), which take into consideration the complexity and number of assessments. The program also initiated the NexGen Risk Assessment pilot project in May 2009, which involves incorporating molecular

systems biology and gene-environment interactions to advance risk assessment, with the goal of evaluating more chemicals in less time.

The old IRIS process involved 26 steps and the new, streamlined process has only 7 steps. The new process allows more control of the scientific review, which accounts for much of the acceleration. Step 4 of the new process includes a listening session, which is designed to increase the transparency of the process.

The HHRA Research Program has quickly demonstrated progress under the new IRIS process. In FY 2006 and FY 2007, only 2 final assessments were posted on IRIS each year. In FY 2008, 5 final assessments were posted on IRIS. In the first three quarters of FY 2009, only 1 final assessment was posted on IRIS; however, after the new process was implemented, 6 final assessments were posted on IRIS in the fourth quarter, and 3 were posted in the first three quarters of FY 2010. Ms. Clark pointed out that in May 2009, there were 15 assessments undergoing interagency review; since implementing the new process, 13 of those assessments have been moved forward. In comparing the actual number of final assessments posted on IRIS with the number targeted in the program metrics, Ms. Clark said that she thinks the program will reach its target for posting in FY 2010.

To address Recommendation 2: *Develop a mechanism for retaining IRIS assessments older than 10 years on the Web site,* the program will:

- ✧ Update assessments that are more than 10 years old and have new studies that may impact a toxicity value or a cancer weight of evidence descriptor.
- ✧ Put assessments requiring extensive analysis into the standard IRIS process; update those with no new data to indicate they are still current.
- ✧ Place assessments requiring limited analysis into the update process (chemicals will be batched).

The IRIS Update Project was started in FY 2009, and the first batch of assessments is anticipated to start the review process in the fourth quarter of 2010. The update process will include the following:

- ✧ A *Federal Register* notice announcing the IRIS Update Project agenda and calling for scientific information.
- ✧ Comprehensive search of scientific literature on each chemical.
- ✧ Draft health assessment development.
- ✧ Combined simultaneous review of the draft by EPA and other federal agencies via the Federal Standing Science Committee.
- ✧ Public comments on draft assessments, followed by independent external peer review under FACA.
- ✧ Final IRIS assessment reflecting public comments and independent external peer review will replace old assessments on the IRIS database.

The HHRA Research Program has made considerable progress in addressing Recommendation 3: *Continue to develop ties with the National Center for Computational Toxicology (NCCT) and provide formal input.* The program participated in the May 2009 NCCT ToxCast meeting. Based on NCEA's suggestion, chemicals on the IRIS agenda or nominated for assessment in the PPRTV program, are being added to ToxCast Phase II. NCEA also is participating in the cross-ORD postdoctoral fellows program, and some NCEA scientists have been detailed to NCCT. Also, NCEA has made joint presentations with NCCT on the future of toxicology and risk assessment. Most importantly, the program is collaborating with NCCT on the NexGen Risk Assessment pilot project. The challenge is to figure out how to take the

toxicity data and translate them into information that is important for risk assessment. Three assessment tiers have been proposed for NexGen.

To address Recommendation 4: *Capture HHRA responsiveness to national emergencies and difficult clean-up sites in overall framework of the program*, the HHRA Research Program is tracking past and present emergency response support activities and is engaged in internal discussions about how to describe this support in the next version of the HHRA MYP. Ms. Clark pointed out that it is very difficult to predict how much effort will be needed to support future emergencies; therefore, NCEA is determining what resources have been needed in the past as one means of estimating what might be needed in the future. NCEA is making an effort to reach out to the regions through the NCEA "Regional Road Shows," which are briefings designed to inform the regions about what NCEA is doing and how the Center might be of assistance to them. They are working to make NCEA the "go to" organization for high quality and rapid scientific support. Some examples of this include: development of the polychlorinated biphenyls (PCBs) exposure estimation tool for PCBs in caulk; review of the University of Michigan Dioxin Exposure Study to provide perspective for Region 5 on how the study results could inform Agency decision making; assistance to Region 7 by accelerating the completion of the hexavalent chromium IRIS assessment; and assistance to Region 9 (Hawaii) and the Office of Air Quality Planning and Standards (OAQPS) on assessing the health risks associated with sulfur dioxide from volcanic activity. In addition, NCEA is assisting with the Gulf oil spill emergency response. These activities include:

- ✧ Dioxin Formation and Risk Assessment
  - – Prepared screening risk assessment for workers and general population.
  - – Informed development of sampling plan measuring dioxin during controlled burns at sea.
  - – Developing approaches that will use measured dioxin emission factors to estimate potential risks to human health.
- ✧ Fish Consumption Rates Assessment
  - – Providing information to characterize fish consumption rates, which will be used with measurements of oil-related contaminant concentrations to assess human health risks associated with consuming Gulf fish.
  - – Collaborating with OW and the Food and Drug Administration (FDA).
- ✧ Risk Assessment for Gulf Swimmers
  - – Assisting OW in developing guidelines to inform decisions concerning risks of spilled oil to swimmers.
  - – Developed risk assessment exposure scenario, the exposure factors used for the scenario, and specific health-based benchmarks.
- ✧ Toxicity of Chemicals in the Gulf
  - – Provided toxicity information for chemicals of concern related to the Gulf oil spill, including those likely to be present in crude oil as well as those used in chemical dispersants.

In response to Recommendation 6: *Consider well developed PPRTVs as source for IRIS assessments*, NCEA reviewed the PPRTVs and found two—cobalt and vanadium pentoxide—to develop into IRIS assessments. The program also has sought advice from the programs and regions on their assessment needs. The highest priority needs will be addressed through IRIS; for more targeted needs, NCEA is consulting with the programs and regions to determine if a PPRTV assessment would meet their needs.

NCEA has taken action to address Recommendation 7: *Steps need to be taken to ensure the transparency of decisions made in the process of performing assessments*. These actions include:

- ✧ IRIS Assessments
  - – Implemented new IRIS process in May 2009, which includes multiple opportunities for federal agency review, external peer review, and public comment.
  - – Incorporated IRIS listening sessions for the public and stakeholders, and briefings for other agencies (e.g., Department of Agriculture, FDA) on high profile chemicals.
  - – Making comments from federal agency review publicly available.
- ✧ HERO (Health and Environmental Research Online)—a database of scientific studies used to develop EPA risk assessments (http://www.epa.gov/hero)
  - – Expanded to include IRIS assessments as they are developed, which allows the pubic to readily access studies on which decisions are based.
- ✧ ISAs and NAAQS
  - – Restructured ISA with concise summary and integrative synthesis of key findings.
  - – Focusing on key policy-relevant findings.
  - – Developed causality framework used in ISAs, which provides transparency and consistency in drawing conclusions and causal judgments.
- ✧ EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments
  - – Defined process clearly for study selection.
  - – Held a scientific workshop (February 2009) to ensure that EPA's response to the National Academies focused on key issues and reflected the most meaningful science.

In response to Recommendation 8: *Consider recruitment of senior scientists*, the program has hired senior Oak Ridge Institute for Science and Education (ORISE) fellows to provide support for complex science issues (e.g., quantitative application of genomics and high-throughput data into chemical risk assessment, mutagenic mode of action). In addition, a senior Division Director has been hired under Title 42. The program is expanding its capacity in LTG 2 (NexGen) with post-doctoral fellows from ORISE, the American Association for the Advancement of Science (AAAS), and ASPH.

NCEA has made some progress in addressing Recommendation 9: *The program is encouraged to make PPRTVs more available for use in hazardous waste site assessments and promote use as appropriate*. The program currently makes PPRTVs available to all EPA staff and by request to state and other partners in waste site assessments. The HHRA Program is reaching out to the program offices (beyond the Office of Solid Waste and Emergency Response [OSWER]) to publicize the existence of PPRTVs. NCEA is engaged in ongoing discussions with OSWER to make the PPRTV database publicly available. It is anticipated that this will happen in the near future.

Several steps have been taken to respond to Recommendation 10: *The program needs to consider information on potential public health as it prioritizes chemicals*. The HHRA Program has participated in extensive meetings with the program and regional offices regarding the selection of priority chemicals. In addition, the process for adding chemicals to the IRIS agenda has been revised to include public health information, to make it more transparent, and to add a "feedback" loop to the programs and regions. The *Federal Register* notice for new nominations includes more transparency on how decisions are made. Public health information (exposure and toxicity) is being considered in identifying priority chemicals. Several phthalates have been added to the cumulative health assessment because of public health concerns. Ms. Clark noted that the phthalates cumulative assessment is the first step in considering risks of exposure to multiple chemicals and it may serve as a framework for extension to other compounds in the future.

Ms. Clark closed her presentation by stating that she is excited about what the program has been able to achieve in the past few years since the BOSC review.

Dr. Sayler thanked Ms. Clark for her presentation and asked if there were any questions. He noted that Dr. George Daston, a former BOSC Executive Committee member who chaired the HHRA Subcommittee that conducted the program review, had joined by telephone and he asked if Dr. Daston had any questions or comments. Dr. Daston said that this program is a cornerstone of EPA's work; so many programs and processes within EPA rely on it. Therefore, the program must be designed and implemented well, and both are true for the HHRA Research Program. These assessments are valued by organizations throughout the world and the demand for IRIS assessments far exceeds the available resources of the program to do the assessments. Dr. Daston indicated that he is very pleased with the effort the program has put into streamlining the IRIS process. The review process (both internal and external) has been an impediment to completing assessments in a timely manner.

Dr. Daston thought the program was doing a good job of leveraging the efforts of other organizations. He was very pleased to see the collaboration with NCCT. He stated that NCEA and NCCT are leaders in their fields and they need to work together to make useful tools available for risk assessments. He encouraged the program to continue this interaction. He stressed the need to be diligent about ensuring the transparency of the process for prioritizing chemicals for risk assessments. Dr. Daston thought the next BOSC program review should assess whether the transparency of that process is adequate. Although the program has attempted to address Recommendation 8, which dealt with recruiting senior scientists, the program has not been able to fulfill the spirit of that recommendation. Therefore, the program should keep this recommendation on its radar screen for future action. Dr. Daston noted that the HHRA Research Program received very good ratings in the last program review and it has taken steps to make the program even better.

Dr. Cozzens asked how the program plans to build emergency response into its program planning. From the presentation, it appears that NCEA is attempting to assess how much effort has been expended on such efforts in the past. Do you have a record of how many full-time equivalents (FTEs) are allocated to emergency response each year? Ms. Clark replied that NCEA is trying to document that effort. Ms. Kacee Deener explained that she has been working on assessing the emergency response effort during the past 2 years so that the program can use this information to predict future effort. There are discussions underway about the best way to incorporate this into the MYP. Dr. Stan Barone acknowledged that this is a difficult task because emergencies are unpredictable; however, having the historical data will be beneficial in planning for future emergency response needs. He added that, in recent years, NCEA has seen an increase in the number of requests for assistance and the time that it takes to respond to these requests. Therefore, this is not just an historical assessment. Dr. Cozzens praised the program for attempting to track its emergency response support. She also suggested that having this information available could be valuable in justifying to OMB why certain performance goals were not met when resources were diverted to emergency response support. Dr. Olden agreed, stating that it is important to communicate what percentage of the program's effort is dedicated to emergency response support and what percentage is devoted to achieving the program's strategic LTGs. Ms. Clark agreed and added that the percentage allocated to emergency response support is probably around 10 to 15 percent. NCEA would like to have a better handle on this, however, so it can set aside resources to meet these needs.

Dr. Tharakan asked if the program had done a risk assessment for the workers responding to the Gulf oil spill. Ms. Clark replied that the program participated in the risk assessment for the workers that was done by the National Institute for Occupational Safety and Health (NIOSH).

Dr. Demerjian asked about the volatilization of the oil, formation of semi-volatile organic compounds (SVOCs), and the photochemical transformation to secondary organic aerosols (SOAs). Is this aspect being considered in the assessment? Dr. Barone responded that ORD is involved in the efforts of the

other federal agencies, and those aspects are being considered. Dr. Demerjian asked if areas around the spill are being monitored to determine its effects. Dr. Barone replied that measurements are being taken real time and the focus is on the safety of the workers. The longer term focus will be the environmental effects, and additional research and monitoring will be needed.

Dr. Philbert asked what is being done on an interagency basis to ensure that appropriate data are being captured now so that they can be used in follow-up research. Dr. Barone responded that a database is being created to store all of the data being collected and the database is being made publicly available on the Internet.

Dr. Olden stated that he did not hear any mention of epigenetic regulation. Is that being considered? Dr. Barone replied that other parts of ORD (e.g., NCCT) are looking at epigenetic regulation. The National Institute of Environmental Health Sciences (NIEHS) National Toxicology Program (NTP) is involved as well. ORD is trying to incorporate this work into its assessment.

Ecosystem Informatics Session

Ecosystem Informatics: Interdisciplinary Graduate Education and Research Linking Ecology, Computer Science, and Mathematics

Dr. Julia Jones, Ecosystem Informatics Program, Oregon State University (OSU)

Dr. Julia Jones explained that ecosystem informatics involves collaboration among natural scientists (ecologists), computer scientists, and mathematicians. It addresses pressing problems of natural resource management and explores alternative approaches to conceptualizing problems, modeling ecosystem processes, and uncertainties.

Important contributions to key problems in ecology include: uncertainty in ecosystem models, predicting extreme events, automatically detecting events and organisms, predicting community response to disturbance, and quantifying species responses to environmental change. The experiences OSU has gained during these collaborative effects provide valuable lessons for educators and resource managers.

Dr. Jones explained that ecosystem informatics does not merge the different disciplines involved but fosters collaboration among them. For biophysical scientists, ecosystem informatics can help with huge data streams from burgeoning sensor networks. It also can help with alternative conceptualizations and models of ecological and ecosystem processes. For mathematical scientists, ecosystem informatics provides the opportunity for developing entirely new methods in computer and mathematical sciences. It also brings together a more diverse study group to contribute to environmental problem resolution. Some ecosystem topics that can benefit from ecosystem informatics include: scaling and uncertainty in cycling of carbon and nitrogen; stability and resilience of ecological communities; natural disturbance processes; temporal and spatial predictions; and structure and function of hierarchical branching networks.

Ecosystem informatics research builds on large datasets and ecological process understanding, develops new models, and compares alternative modeling approaches.

The work on ecosystem informatics began at OSU with the award of a National Science Foundation (NSF) Interdisciplinary Graduate Education and Research Training (IGERT) program grant in 2003. The effort was initiated by Long-Term Ecological Research (LTER) senior natural scientists who asked mathematicians and computer scientists to collaborate to expand the scope of LTER. In 2005, the Ecosystems Informatics program had its first Ph.D. students and OSU hired two young faculty members. In 2007, there were 15 Ph.D. students in the program and OSU hired three more young faculty members. By 2009, there were 30 Ph.D. students, the faculty was getting additional grants, and two postdocs were hired.

Dr. Jones described a study of the collaborative networks in the ecosystem informatics group. The study found that 87 percent of new ties in the program were with people in different departments; 50 percent of the collaborative ties resulted in new ideas that could not have been produced individually; 68 percent of new idea ties were between fields; and 76 percent of new idea ties were between departments. She noted that working together has produced ideas or findings that could not have been produced individually or by a single department.

One example of ecosystems informatics research involved the problem of habitat selection. Organisms do not select the first habitat they encounter. They visit some number of habitats and then select one. The "refractory period" is the time spent visiting habitats before making the selection. This is a mathematical problem—to select the optimal stopping time. What is the optimal number of potential habitats to visit before selecting one? The optimal "refractory period" is n/e where n = total number of possible habitats and e = natural logarithm. How can we use this problem to understand organism behavior in space?

Another example of ecosystems informatics research focused on the question: How do the spatial dynamics of emergent stream insects affect population dynamics? The mechanisms are drift and flight. The "critical domain" is the minimum size of habitat required to maintain persistence of a population. In a single channel, the answer is a length, but in a stream network, the answer is more complex. What is the effect of network structure on time to extinction? What is the effect of arrangement of predators (fish) on time to extinction? The outcome of interest is a threshold controlling the balance between survival versus extinction; the threshold depends upon the balance of diffusion (Brownian motion) versus velocity.

A third example of ecosystems informatics research concerned fire effects on forest stand dynamics. How does non-stand-replacing fire affect forest stand age distribution? How does time-varying fire affect forests? Hazard rate is used to formulate the model and it is solved analytically. This yields a model that can predict how long it will take for a forest stand experiencing a change in fire return interval to reach a new equilibrium.

A fourth example of ecosystems informatics research involved anomaly detection. Many environmental sensors produce large datasets (temperature, carbon flux, etc.) and the data contain erroneous observations. How does one automate the process of error detection? Machine learning ~~with~~ of Bayesian hierarchical models provides the necessary quality control. This is done by creating a probabilistic model of the domain, represented by a Bayesian Network. The process model (how the true temperature behaves) models normal behavior, and the observation model (how the temperature is measured by the sensor) includes ~~the~~ a generic fault model. If the difference between the sensor reading (O) and computed P (process model) is large enough, then an anomaly is declared. An ideal quality control model should produce two things: (1) a label that distinguishes data anomalies, and (2) an imputation of the true value (with some confidence measure).

A fifth example of ecosystems informatics research concerns bioacoustics. Many organisms are difficult to census (e.g., birds). Acoustical recordings of these organisms may help detect their movement and abundance. New low-cost sensors provide continuous audio data, and machine learning can automatically identify bird songs in recordings.

A final example of ecosystems informatics research involves species modeling. Many species have been monitored (e.g., birds) and the datasets are large and of variable quality. These long-term datasets contain information on species' responses to climate variability and machine learning can infer species distribution (single or multiple species). The goal of a multiple-species model is to simultaneously predict the occurrence of multiple species. It offers the advantages of identifying and understanding communities, detecting competitive exclusion, exploiting inter-species correlations to improve prediction accuracy, and predicting hard-to-detect species based on easy-to-detect species (e.g., detect understory

based on canopy). The three methods are to model each species separately (M0), model each species separately but perform model selection jointly (joint model selection, M1), or capture the correlation structure among the species (M2). It is hypothesized that M2 will be better than M1, and M1 will be better than M0. Seven different modeling methods for species distribution of birds at Hubbard Brook were compared and it was determined that stacked random forests (a model of type M2) were best for this dataset and measure.

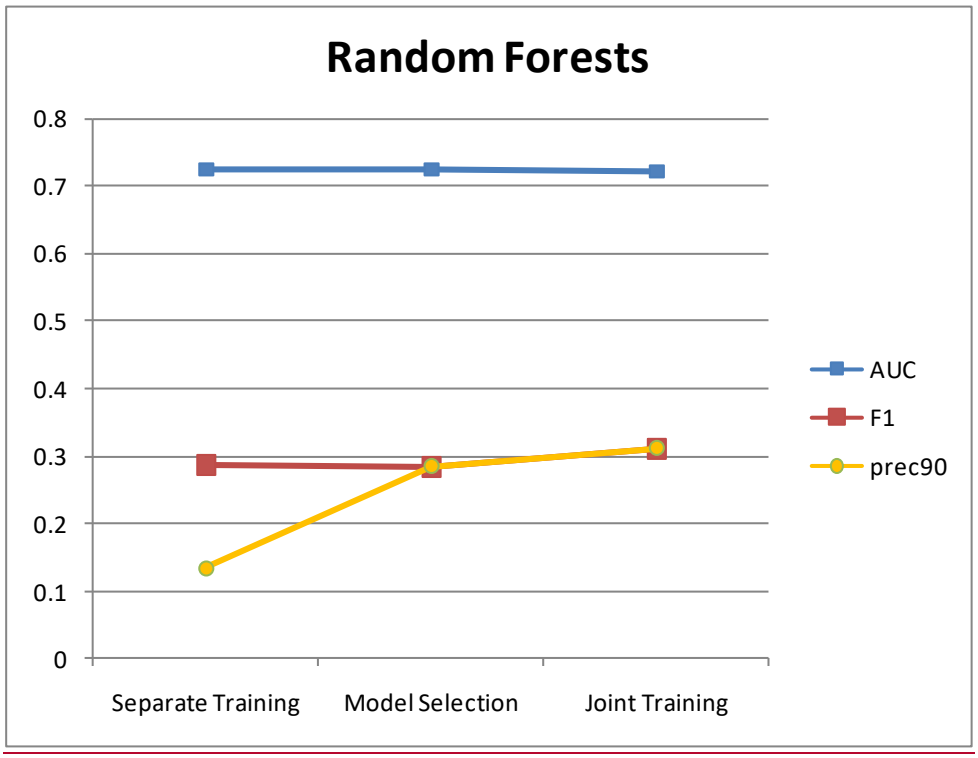

Figure comparing the performance of three metrics (AUC: area under the ROC curve; F1: harmonic mean of precision and recall; prec90: precision at 90% recall) for predicting the distribution of 34 species of birds at Hubbard Brook LTER (data from Matt Betts, OSU).

In summary, Dr. Jones stated that ecological problems offer many challenging opportunities for mathematicians and computer scientists. Collaborations of ecologists with computer scientists and mathematicians can address major problems in environmental science and contribute to sustainable management of ecosystems. These collaborations require significant investment of time and energy by senior faculty in participating disciplines, and they can enhance participation and diversity in science, technology, engineering, and mathematics (STEM) disciplines. They also help to create a workforce trained to succeed in the new information-based, highly technological society. Successful collaborations in ecosystem informatics involve exposure to ecosystem and resource management issues in shared field experiences, interdisciplinary communication for problem formulation, attention to disciplinary and interdisciplinary balance, committed senior researchers, and development of a network of collaborators. These collaborations can contribute fundamental insights to basic and applied ecology, and also may lead to new advances in computer science and mathematics.

Dr. Jones then asked if there were any questions. Dr. Olden asked about validating the ecosystem model. Do you make predictions and then see how close they are to reality using a standard procedure for validation? Dr. Jones replied that the model is validated using data that were not used to build the model. She also noted that it is important to make sure that the methods do not take advantage of scale. They use the same type of validation that is used in other fields (e.g., validate against standard bioassays and pathology).

Mathematics of Ecological Dispersion

Dr. Enrique Thomann, Department of Mathematics, Oregon State University

Dr. Thomann referred to the project on the effects of fire on forest stand dynamics that was mentioned by Dr. Jones in her presentation. Initially, there was a significant communication barrier between the ecologist and the computer scientists working on this effort; however, after some time the ecologist began asking questions that were almost mathematical. It is important for the ecologists and the computer scientists to use a common "language." For this project, the ecologist had to figure out if he wanted to develop a model that would predict the future or detect the effect of changes.

Dr. Philbert asked if the "language" they developed was universal. If a group on the East Coast carried out a similar project, how similar would their "language" be to that developed for this OSU project? Dr. Thomann replied that the language is not universal and this effort is just the beginning of developing such a language. A great deal of effort must be expended in the beginning to communicate and describe the project and what needs to be done. After there is agreement on definitions, the project can move forward.

Referring to two graphs that were included in Dr. Jones' presentation, Dr. Sayler asked if they were generated from a model or from actual data. Dr. Thomann replied that they were generated from the model. Dr. Sayler commented that this almost becomes a sensitivity analysis to point the researcher in a particular direction. Dr. Thomann responded that it identifies different age classes and how long it will take to transition from one to another.

Dr. Tharakan asked if it was possible to take the ecosystem informatics model and work backwards to see if it accurately modeled the changes. Dr. Thomann answered that it was an important part of the thesis for this project to use historical data to assess the accuracy of the model. He added that the data could not justify strong conclusions. Dr. Jones mentioned that this student began as a field scientist who had a math phobia; however, he was drawn to complex computer simulations to explain what he was observing in the field. Therefore, he collaborated with mathematicians to develop an analytical model that did a much better job at explaining the observations than a simulation model. Dr. Sayler commented that, now that the processing power is available, the issue is how to assemble and interpret the data. Dr. Philbert stated that when a human population is exposed to some drug, only a small subset of people have an adverse effect. Can such singularities be detected with this model to explain why individuals in a group behave differently? One participant replied that it would be difficult because trees can reproduce asexually and they do not grow in a constant temperature. In some forests, there has not been a fire for 1,000 years, and other forests burn frequently. Dr. Jones noted that different species of trees respond differently to fire. The model could detect that difference by age of tree and species. This approach could be applied to detecting the singularities to which Dr. Philbert referred. She added that one colleague is looking into how to predict disease epidemics with this model. A participant commented that one of the advantages of this model is that it goes from a conceptual view to a more rigorous mathematical view to help explain phenomena.

Dr. Haas observed that the OSU collaboration works because that organization has ecologists, mathematicians, and computer scientists who are used to inquiry-based research. EPA, for the most part, relies on contractor-based mathematical and computer science support rather than internal staff. Could that restrict the degree of cross-over interaction at EPA? Dr. Demerjian thought that collaboration would more likely be restricted because of the discipline. He noted that ecologists do not have a long history of building models. In addition, it is difficult to find 50 years of data to offer an adequate dataset. Dr. Thomann commented that an ecologist would typically rely on computer simulation to explain observations; however, that is not the approach that would be used by a mathematician. One participant mentioned that there has been some reluctance at EPA to hire mathematicians because the Agency is an applied science organization and it is not obvious where a mathematician would fit in. In addition, computer scientists usually are not viewed as part of the interdisciplinary team solving an environmental problem.

Computer Science and EcoInformatics
Dr. Tom Dietterich, Director of Intelligent Systems Research, School of Electrical Engineering and Computer Science, Oregon State University

Dr. Tom Dietterich described two data driven science projects: (1) Species Distribution Modeling and (2) Computer Vision for Automated Identification of Arthropods. The Species Distribution Modeling project involved predicting spatio-temporal distribution of species (single and multiple). The model could be used for: species mapping to guide field surveys, reserve design to optimize conservation benefit versus cost of acquisition/opportunity costs, and real-time management of barriers to bird migration (skyscraper lighting, wind farm operations, airplane-bird interactions). OSU collaborated with the Cornell Lab of Ornithology's Ebird.org, which is a real-time, online checklist program that provides basic information on bird abundance and distribution at a variety of spatial and temporal scales. Volunteer "birders" upload checklists of birds observed and not observed. Ebird.org receives 1.5 million data points per month, from birders with a wide mix of expertise. The challenges for the Species Distribution Model are fourfold:

1. Detectability—Bird may be present but not be detected by observer.
2. Experts versus Novices—Novices are more likely to fail to detect, and they may confuse a bird with other species.
3. Sampling Bias—Birders stay close to home so the sampling is skewed to human population centers.
4. Partial Information—Observations may provide only partial information.

Dr. Dietterich stated that birds are most detectable during migration and mating. Models that ignore detectability can become confused (e.g., predict that forests are poor bird habitat in July and August). Detectability depends on the observer and his/her effort as well as the species, time of year, density of vegetation, weather, and other factors.

Occupancy/detection models (Mackenzie et al.) attempt to ~~explain what happened~~separate occupancy and detection given the observation data by using two logistic regression models—one for occupancy and one for detection probability. In machine learning, the logistic regression models are replaced with boosted regression trees (BRTs), which are known to be one of the best methods for species distribution modeling under perfect detection. This novel~~e general~~ BRT methodology can handle ~~many~~ latent variable models unlike existing BRT methods.

To address the challenge of birder expertise, they looked at what species the novice birders over- and under-~~-~~reported. They also estimated the expertise level of each birder. The hypothesis was that the Species Distribution Modeling accuracy could be improved by down-weighting (but not discarding) novice data. This added an expertise component to the Occupancy/Detectability model. As the model becomes more sophisticated, it will be able to make better predictions.

Because the citizen scientists reporting observations stay fairly close to home, the sampling tends to be skewed to ~~the~~ human population centers. The challenge was how to make good predictions across the entire United States. They accomplished this by using covariate shift reweighting. They confirmed that the weighting approach improved the model results.

Dr. Dietterich noted that partial information comes from, for example NEXRAD weather radar, which provides an approximate measure of the number of birds but does not indicate the species. Similarly, night flight calls are a diagnostic for some species, but not for others. These data can be incorporated using a collective Hidden Markov Model (cHMM), which provides algorithms for inferring the most likely state and path.

Dr. Dietterich indicated that direct observations of bird migration (e.g., by radio tagging) are limited. The goal of BirdCast, a pilot radar ornithology project that focuses on the mid-Atlantic region, is to generate real-time migration forecasts. These data will help scientists understand how birds "decide" when to continue along their migration path, how they "choose" their path and where they decide to stop over, and predict how climate change and land use will affect these decisions. The data also can be used to identify and remove migratory hazards; for example, reduce lighting in skyscrapers during major migrations, manage wind farms to minimize migration interference, and alert air traffic to bird/plane collision risk. The data also provide birders with information on where and when they can observe target species.

Dr. Demerjian asked if anyone had done any correlations with weather patterns and conditions. Dr. Dietterich replied that the current belief among ornithologists is that, for short-distance migrations, the birds usually wait for favorable winds, but for long-distance migrations, the birds have a particular time that they must leave.

The second data driven science project described by Dr. Dietterich was ~~the~~ Computer Vision for Automated Identification of Arthropods. He explained that arthropod population surveys of freshwater streams are used for assessing stream health, measuring the success of stream restoration, and understanding basic stream ecology. This project involved the development of a new survey concept in which the technician would collect the samples in the field and manually clean the samples. The specimens would be dumped into a robotic device that automatically singulated, photographed, identified, and sorted them. An expert would manually identify the "rejects."

The pilot project focused on using this new survey concept to identify nine taxa of stoneflies. There were 3,826 stonefly images; 773 specimens and 9 classes were identified. The error was estimated by threefold cross-validation. The error rate using the state-of-the-art method was 16.1 percent, and the error rates for pilot Method 1 (using boosted dictionaries) and Method 2 (using stacked evidence trees) were 4.9 percent and 5.6 percent, respectively.

The current work is focusing on identifying the 50 most abundant taxa of Ephermeroptera, Plecoptera, and Trichoptera (EPTs), which are the basis of EPA Environmental Monitoring and Assessment Plan (EMAP) surveys. The EPTs are identified independently by two experts. The initial results for 29 taxa indicate that the precision varies from species to species. The challenge is detecting and rejecting "novel" species. Can the system detect that a specimen does not belong to any of the training classes? This question poses interesting problems for the computer scientists.

Dr. Dietterich closed his presentation by identifying the next steps for this project, which are to improve shape descriptors, conduct tests on EMAP specimens, initiate the soil mesofauna project, improve the rejection of distracters, and initiate *in situ* video surveillance. He asked if the BOSC members had any questions.

Dr. Philbert asked if Dr. Dietterich had looked at the pathology literature on the automated reading of pathological slides. Dr. Dietterich responded in the affirmative, particularly for breast cancer tissues. OSU's goal is to develop something similar. Dr. Philbert suggested that Dr. Dietterich contact Dr. Daniel Farkas, Bioengineering Department, The Weizmann Institute of Science at the University of Pittsburg and Dr. Simon Watkins, Department of Cell Biology and Physiology at the University of Pittsburgh School of Medicine about the work they are doing. Dr. Philbert asked if the specimens were dead and Dr. Dietterich confirmed that they were and that they were preserved in alcohol.

Dr. Haas asked if the stonefly data were from local streams, and Dr. Dietterich replied that they were collected in streams from New Mexico to Oregon. Dr. Haas then asked if they had looked at the value of incorporating contextual information. Dr. Dietterich indicated that they had not, and added that his dream is to develop a retrainable technology that can be used for many problems.

Dr. Sayler thanked Drs. Jones, Thomann, and Dietterich for their presentations.

Ecosystem Informatics Framework for Marine Biogeography and Natural History at Regional to Global Scales

Dr. Henry Lee II, EPA, ORD, NHEERL, Western Ecology Division

Dr. Henry Lee explained that the present goal of this effort is to capture the global biogeographic distributions of all the near-coastal nonindigenous species in the North Pacific along with their relevant habitat and invasion traits. The future goal is to adapt the Pacific Ecosystem Information System (PCEIS) to capture climate related traits for near-coastal species in the Northeast Pacific and Arctic. The database then could be used as a knowledge engine for generating species' climate risk profiles.

The basic principles and assumptions are: (1) for many questions, classes for habitat requirements and/or physiological tolerances will suffice; (2) information will be capture by hierarchical classes where possible to accommodate different levels of knowledge and needs; (3) geography is biology—use distributions to infer habitat specificity; and (4) queriable natural history requires standardization even at the loss of some ecological nuances. A graphical interface is used for capturing distributions of native and nonindigenous species because this is much easier to use than a spreadsheet format.

The first step in the management strategy for the research data is to develop an informatics topology to collect and store biological data. The regional and local databases from EMAP are feeding into the database. Presently, more than 17,000 taxa are in PCEIS. The objective is to have at least 95 percent of the reported species in the Northeast Pacific and Arctic for fishes and most invertebrate taxa. Dr. Lee presented an atlas of the nonindigenous species in the North Pacific and then did a brief demonstration of PCEIS.

According to the Millennium Ecosystem Assessment, biodiversity will decline globally if there is a continued focus only on ecosystem services. Dr. Lee noted that although extinction is the ultimate ecological insult, there are many lesser insults, including population decline, range contraction, population fragmentation, and loss of associated ecosystem functions for services. The objectives of the project are to: (1) develop automated procedures to identify near-coastal species at greatest risk to different types of climate alterations using rule sets based on biogeographic distributions, natural history attributes, and physiological traits; (2) overlay species' biogeographical and habitat distributions with projected climatic alterations at multiple scales; and (3) analyze risk for suites of taxa from the Gulf of California to the Arctic.

The Arctic is predicted to experience larger temperature increases than the mid- and low-latitudes. Additionally, polar species have "nowhere to run" in response to a warming ocean. The results of this effort can be used to help shape public opinion and policy, identify locations that will be most impacted by climate change, identify types of climatic alterations that will have the greatest impact on biodiversity, and develop potential mitigation options. Dr. Lee presented a framework for a climate-induced alternative futures species distribution prediction system. He noted that, because of the complexity of the rule sets, PCEIS will migrate from Access to the Web.

The International Union for Conservation of Nature (IUCN) Red List approach needs to be modified for climate risk, specifically for near-coastal species. EPA needs to work with the IUCN more closely in the future to accomplish this. A major challenge is that there is considerably less data available for near-coastal species than for terrestrial flora and fauna. Vulnerability is being predicted based on the three components of rarity. Multidimensional analysis of rarity types is based on Rabinowitz's Rarity Classes (which are similar to the criteria used by the IUCN for its Red List). The first component of rarity is whether the species has a high or a low population size. The second is whether the species has a large or small geographic range. The third component is whether the species can occur in a broad range of

habitats or whether it is restricted to a more narrow range. How vulnerable is the habitat to different types of climatic alterations?

Data from PCEIS can be used to assess, for example, the species of chiton in the Northeast Pacific (Gulf of California to Chukchi Sea) that are most at risk to temperature increases or those most at risk to ocean acidification. The number of species endemic to each ecoregion and the number of species in more than one ecoregion were identified. A cross-walk between ecoregions and depth was done using the PCEIS depth classification schema. Dr. Lee presented the preliminary rule set for pCO_2 and ocean acidification organism traits affecting vulnerability. He noted that developing these rule sets is a large part of the research. One possible output could be a color-coded matrix that identifies the risk to climate change (e.g., increase in air temperature, increase in water temperature, loss of wetland habitat) for various species.

Ms. Zhuikov asked if the PCEIS database is available to those outside of EPA. Dr. Lee responded that the Agency will make a version of PCEIS available to the public in October 2010. This version will contain information on about 1,000 non-native species in the North Pacific. EPA has an interagency agreement with the U.S. Geological Survey (USGS) to get the database online. Ms. Zhuikov said she thought that the U.S. Fish and Wildlife Service had an invasive species database. Dr. Lee replied that it is USGS that has that database. He added that EPA is working with USGS and also is trying to connect with the Smithsonian and its database. Dr. Lee mentioned that there are several hundred nonindigenous species databases.

Dr. Sayler asked if there were any international connections. Are other countries attempting to do anything like this? Dr. Lee responded that the work is funded partly by the Japanese. WED has had no success in working with China, and limited success with Canada because the database will not run on Canadian systems. Dr. Lee said that WED hopes to foster the relationship with Japan.

Dr. Olden asked how many species have been entered into PCEIS and if there was a limit to the number it can contain. Dr. Lee replied that they have data on all of the fish on the West Coast and PCEIS will include all of the major taxa. Dr. Haas asked if there is a precise definition of a native species. Dr. Lee answered that they are considering native species that are from the pre-Columbian era. Dr. Demerjian asked if the database users are entering data into the PCEIS. Dr. Lee replied that Microsoft Access does not allow multiple, simultaneous users, but he can take the back ends and merge them. Unfortunately, this approach makes Dr. Lee the gatekeeper. Dr. Demerjian asked about quality control and Dr. Lee said that he is responsible for quality control at this point. Dr. Philbert pointed out that allowing users to enter data makes quality control much more difficult because these users operate under different assumptions. Dr. Lee agreed and added that there is a user's manual and documentation for the database.

Laboratory Tour: Western Ecology Division

Modeling Ecosystem Service Tradeoffs in Response to Land Use and Climate

Bob McKane, EPA, ORD, NHEERL, Western Ecology Division

Dr. Fontaine introduced this presentation by Dr. Bob McKane, which was prerecorded, from the Ecosystem Services Research Program (ESRP) Seminar Series held July 1, 2010.

WED is involved in developing ecosystem service tradeoffs for alternative forest management scenarios in support of the ESRP. The seminar included: an overview of the VELMA ecohydrology model and goals; monitoring, mapping, and modeling demonstration (forest management alternatives and ecosystem service tradeoffs); the decision support framework ENVISION VELMA; and current place-based applications and clients (Willamette Ecosystem Services Project and Flint Hills Regional Applied Research Effort [RARE]). Dr. McKane noted that the work described in the seminar is the collaborative effort of EPA, Georgia Institute of Technology, Kansas State University, Marine Biological Laboratory–

Woods Hole, and OSU.

Interaction of processes across wide spatial and temporal scales requires a systems approach for managing bundled ecosystem services. An example of an ecosystem service is water quality and the supporting processes are transforming and retaining nutrients and toxics in plants and soils.

Everything is interconnected so if actions are taken to optimize one ecoservice, others will be affected. A model is needed to show this interconnectedness across large landscapes. That model is the Visualizing Ecosystems for Land Management Assessments (VELMA) Ecohydrology Model. VELMA is a soil column based model (30 x 30 meters pixels or grid). It helps communicate the transport of materials down slope. The pixel size can be changed if necessary and the data needs of the model are simple.

The features of this model include: coupled hydrological and biogeochemical cycles; flexible landscape units and soil layers; and spatially explicit soil and vegetation dynamics–days to centuries, plots to basins. The goals are to develop a model that: (1) links effects to causes (identify processes controlling ecosystem service tradeoffs), (2) is applicable to a wide variety of ecosystems and regions, (3) maps "bundles" of ecosystem services across a wide range of spatial and temporal scales, (4) is easy to implement (data and calibration requirements), and (5) provides a user-friendly decision support framework to assess outcomes of alternative policies and management decisions. VELMA simulates the effects of climate, land use, land cover, and soils on multiple ecosystem services (water quality and quantity regulation, food and fiber production, carbon sequestration, greenhouse gas regulation, and regulation of reactive nitrogen [Nr]).

VELMA has a very simple hydrological submodel. It computes the soil water balance daily for individual pixels, typically represented at 30 x 30 meters soil columns divided into four layers. Drainage and runoff occur as a function of soil moisture content, which is related to soil porosity. For sandy soils, the logistic curves for drainage and runoff would shift to the left; for clay soils, the curves would shift to the right.

VELMA also has a biogeochemical submodel that computes the exchange of carbon and nitrogen between the atmosphere, soils, plants, and streams. VELMA links the hydrological and biogeochemical processes within hill slopes and watersheds. The goal is to develop a model that is broadly applicable; for example, it will work for the Arctic LTER, Hubbarb Brook LTER, Chesapeake Bay, Konza Prairie LTER, and HJ Andrews LTER.

The Willamette Ecosystem Services Project is focused on the HJ Andrews Experimental Forest and LTER site, which is located in the Willamette River Basin (approximately 30,000 km^2). The Willamette River Basin is 70 percent forest, 20 percent agriculture, 8 percent urban, and 2 percent wetlands and other. It is flat with rich fluvial soils that are excellent for production of fruit, grass seed, and other crops. This study is a good example of how monitoring, modeling, and mapping can be used together to support decisions.

An ESRP workshop was held in Corvallis in May 2010, which facilitated the exchange of information among those doing monitoring, those doing modeling, and those doing mapping. Monitoring provides data on ecosystem service indicators (status and trends); modeling links ecosystem services effects to specific stressors and provides alternative future ecosystem services projections; and mapping provides a national atlas and maps of ecosystem services (status and trends). Communications among these three areas is critical to support client decisions, including problem formulation; scenario definition; ecosystem services metric needs; integration of data, scenarios, and models; and assessment of tradeoffs.

Dr. McKane presented several graphs and explained that the model was calibrated to simulate the dynamics of forest biomass following a fire and following clear cutting in the Pacific Northwest. The model was validated against local and regional scale data. The graphs showed that following clear cutting

in 1975, the plant biomass only recovered to about 80 percent of the post-burn effect. Because logs (and nutrients) are transported offsite in clear cutting, the nutrient level is reduced. The area could be fertilized to replace the lost nutrients, but that would have an impact on the stream. The model allows decision makers to look at the effects of that scenario. Dr. McKane explained that the lower graphs compare the observed and simulated stream response to temperature. The model did a good job of simulating the stream's response.

VELMA also did a good job of capturing the data on an old growth forest before it was clear cut in 1975; there was good correlation ($R^2 = 0.91$) between the simulated streamflow and the observed streamflow. Following the clear cut in 1975, the model also did a good job of simulating streamflow ($R^2 = 0.91$). Clear cutting induced a 28 percent increase in annual average streamflow during the first 5 years after harvest, and a 4 percent increase after 25 years.

The hydrologic model held up well when validated across multiple spatial scales. There was good correlation between observed and simulated stream discharge as well as observed and simulated steam chemistry. Dr. McKane noted that the rain starts in the study area in late September/early October. The soil is like a sponge and it must get saturated before the waterflow begins. Therefore, streamflow increases only after the hill slopes saturate, which leads to greater nutrient flushing.

The biogeochemical model was validated on post-clearcut stream chemistry. There was good correlation ($R^2 = 0.86$ for 1994 – 2006) between observed and simulated dissolved inorganic nitrogen (DIN) stream losses; there also was good correlation between observed and simulated dissolved organic carbon (DOC) stream losses ($R^2 = 0.81$ for 1994 – 2006). Dr. McKane said that there are plans to do more spatially extensive biogeochemical validation. He noted that the model did a good job simulating recovery following the stand replacing fire in 1525.

Dr. McKane stated that the model can be used as a mapping tool. He showed maps of simulated plant and soil carbon in the HJ Andrews landscape. The maps reflect the fire and harvest history in the area.

VELMA was used to model three alternative land uses for the 64 km^2 HJ Andrews Basin. Scenario 1—all old growth (historic)—has maximum ecosystem carbon stocks, maximum carbon sequestration, maximum greenhouse gas sink, less stream discharge (25% less), and minimal stream nitrogen load. Scenario 2—all clear cut (hypothetical)—offers reduced ecosystem carbon stocks, less carbon sequestration, greenhouse gas emissions source, and maximum stream discharge and nitrogen load. Scenario 3—present-day landcover (~45% harvested, ~55% old growth)—has some ecosystem carbon stocks (more than Scenario 2 and less than Scenario 1), some carbon sequestration (more than Scenario 2 and less than Scenario 1), greenhouse gas sink (more than Scenario 2 and less than Scenario 1), some stream discharge (more than Scenario 1 and less than Scenario 2). There are tradeoffs among the three scenarios; for example, with Scenario 3, there is less carbon sequestration but some of the smaller streams may not go dry in the summer season. The model does not make value judgments; it just provides the science to inform policy decisions. There is work ongoing to incorporate a habitat biodiversity link to the model.

VELMA has been applied successfully at various scales, from stands to catchments to basins to landscapes (2,000 km^2 are surrounding JH Andrews). The model is being linked with Envision, a GIS-based tool for constructing alternative future scenario applications for community and regional planning and environmental assessments.

Envision was created by OSU to allow examination of the nature and properties of coupled human and natural environmental systems. It employs scenarios, data, and evaluative models produced by past research, and utilizes prior work in agent-based modeling and biocomplexity theory. Central to Envision, are the three-way interactions of actors, who have decision-making authority over parcels of land, the landscape which is changed as these decisions are made, and the policies that guide and constrain

decisions. Envision enables multi-model linkages, and additional ecological models (e.g., HexSim, FishNet) are being integrated as plug-ins. Work is underway to link all of the models (for stressors, ecology, terrestrial services, and aquatic services) into a common framework. To demonstrate some of the features of Envision, Dr. McKane presented a "flyover" visualization of Puget Sound alternative futures—current conditions, unconstrained growth, managed growth, and status quo. The visualizations allow decision makers to view the patterns of carbon storage across the landscape of the various scenarios. The goal is to produce animations that help decision-makers visualize the impacts of various decision options. Dr. McKane commented that this is a good example of linking basic research to societal needs.

At this point, Dr. Fontaine stopped the recording because of time and asked if there were any questions. Dr. Demerjian asked about the 30 x 30 meters resolution. Is there a profile of the soil every 30 meters? Dr. Denis White replied that the selection of 30 x 30 meter pixels is based on digital elevation models. He noted that 30 meters is used because 30 meters resolution is standard for satellite data (Landsat is 30 meters). The soil data are for arbitrarily shaped polygons on soil maps. He mentioned that they use LTER sites because a lot of this work already has been done for these sites.

Dr. Olden commented that the policy makers need information on water runoff, greenhouse gas emissions or recapture, and habitat and biodiversity. Not all of these have been integrated into the model yet so inputs are needed from other sources. An information management tool is needed that will predict the impacts of alternative land management decisions so that the decision makers can assess the tradeoffs. Dr. White responded that Envision is the tool that will provide that information. It can integrate fish models, ecological models, timber harvesting models, and water quality models to provide the information needed to assess tradeoffs.

Dr. Sayler asked if emergy is being used as a subcomponent of these models to look at sustainability. Dr. White answered that Dan Campbell at Narragansett is involved in such work. He added that emergy is one of the factors included in a study in the San Luis Valley area that WED is working on with the Cincinnati laboratory. An EPA report on this work will be released soon.

Dr. Haas asked if it would be helpful to get input on stakeholder preferences, noting that they have different preferences. Dr. White responded that there has been some work with Envision to incorporate the values of decision makers. Dr. Olden cautioned against getting involved in the policy side; Dr. Haas said there is a fine line between developing tools for decision makers and making the decisions and establishing policy. Dr. White stated that the tool can show the decision makers the environmental impacts of their decisions. Dr. Olden commented that this is good science but most Americans would not know anything about this work. Ms. Zhuikov asked if ORD had someone working on communicating this research to the public. Dr. Fontaine responded that this research is quite new and ORD will ensure that it is communicated to the appropriate audiences as well as the public.

Dr. Sayler thanked Dr. Fontaine for sharing the presentation with the BOSC and adjourned the meeting for the day at 5:19 p.m.

TUESDAY, JULY 13, 2010

Dr. Sayler called the meeting to order at 8:35 a.m. He then asked Dr. Sally Darney if she was ready to begin her presentation.

ORD Response to BOSC Human Health Report

Dr. Sally Perrault Darney, EPA, ORD, NPD for Human Health

Dr. Sally Darney explained that she has been acting as the NPD for the Human Health Research Program (HHRP) since January 2008. The BOSC review of the HHRP was conducted in January 2009, and the report on the review was transmitted to ORD in December 2009. ORD prepared a response to that report and transmitted it to the BOSC in June 2010. She stated that this presentation summarizes the ORD response.

The BOSC Subcommittee that conducted the review had a good mix of interdisciplinary expertise, including toxicologists, exposure scientists, public health experts, epidemiologists, and modelers. Dr. Darney noted that social science expertise was absent from the Subcommittee. She indicated that the BOSC review provided valuable feedback for the program and significantly influenced ORD's thinking.

The Subcommittee was charged with evaluating the HHRP's relevance, structure, quality, coordination/ communication, performance, and scientific leadership. The BOSC indicated that the program had matured since the 2005 BOSC review, and increased its emphasis on public health. The BOSC found the program to be robust and that it was responsive to emerging issues. The scientific content of the HHRP was deemed to be excellent by the BOSC and the program was better integrated than at the 2005 review. The BOSC found the program's productivity to be strong with formidable impact. In addition, the BOSC thought the program's leadership was excellent to outstanding.

The overall rating for the HHRP was meets expectations. The ratings for the program's LTGs were:

- ✧ LTG 1–Use of Mechanistic Data in Risk Assessment: Meets Expectations
- ✧ LTG 2–Cumulative Risk: Meets Expectations

- ✧ LTG 3–Susceptible and Vulnerable Populations: Meets Expectations (the children's health component exceeds expectations)
- ✧ LTG 4–Developing Tools to Evaluate Risk Management Decisions: Exceeds Expectations.

Dr. Darney noted that the goals are interrelated and the BOSC suggested that ORD revisit this structure.

The BOSC offered a number of general recommendations for the program. These included:

- ✧ Add linkage with risk assessment—document use of models and tools.
- ✧ Translate research to bring the exposure and toxicology science to bear on epidemiology and community work and thereby address real world public health problems.
- ✧ Make tools and models more "user-friendly" and Web-based.
- ✧ Consider altering the program structure to do these things.
- ✧ Expand partner engagement (generally for all health programs) both within EPA and with other agencies, institutions, and non-governmental groups.

In the original concept, the HHRP was considered a core program that supported other ORD research programs, such as SP2, EDCs, and Clean Air. The HHRP also has tried to be responsive to many questions that arise within the different program offices.

Since the January 2009 review, there have been a number of changes in ORD that affect the HHRP. The new integrated interdisciplinary SPSW Program under development will integrate exposure science, toxicology, and context-specific assessment approaches. Dr. Darney said that she is supportive of the new SPSW Program because it brings the clients into an integrated program and makes communication easier.

There are many drivers for his new program, including:

- ✧ NRC's *Toxicity Testing in the 21st Century* (2007)—highlights need for high throughput, smarter testing.
- ✧ *EPA's Strategic Plan for Evaluating the Toxicity of Chemicals* (2009)—emphasizes use of computational toxicology approaches to elucidate pathways of toxicity and develop predictive models (interagency Memorandum of Understanding with NIEHS, Agency for Toxic Substances and Disease Registry [ATSDR], FDA, and National Institutes of Health [NIH]).
- ✧ NRC's *Science and Decisions: Advancing Risk Assessment* (2008).
- ✧ Administrator's five goals for EPA's new strategic plan include "Assuring the Safety of Chemicals."
- ✧ ORD/AA Paul Anastas' focus on green chemistry approaches and the over-arching theme of sustainability.

It is envisioned that there will be a new HHRP theme to address the Administrator's priority of healthy people in sustainable communities. The program will support the priorities of assuring the safety of chemicals, cleaning up our communities, working for environmental justice, building strong state and tribal partnerships, and protecting children and other vulnerable groups.

Components of the HHRP would be incorporated into the new SPSW Program, including the research for LTGs 1 and 2 and part of LTG 3. This would include: Exposure Models, Factors, and Databases (Exposure Factor Handbooks [NCEA], reverse dosimetry models); Cumulative Risk of Pesticides and

Disinfection Byproducts (e.g., Pyrethroids Scientific Advisory Panel, 2012); Toxicity Pathways (with NCCT); Virtual Liver/Embryo (with NCCT); PB/PK and BBDR Models to link exposure and health effects; Intrinsic Susceptibility Factors (life stage, gender, (epi-)genetics); Biomarkers of Exposure and Effect; and Interpretation of Biomonitoring Data (e.g., NHANES data and risk assessment).

The new HHRP with its theme of healthy people in sustainable communities would focus on EPA goals and emerging issues, including working for environmental justice and protecting vulnerable populations (especially children). Dr. Darney reported that Special Assistants have been appointed for Children's Health (Peter Grevatt) and Environmental Justice (Lisa Garcia). In addition, the Office of Sustainable Communities recently was formed within the Office of Policy, Economics, and Innovation (OPEI). The National Children's Study (NCS) provides partnership opportunities for EPA, and the Agency is a key partner of the Interagency Task Force on Environmental Health and Safety Risks to Children. In addition, there is a growing need for the Agency to address environmental justice concerns. EPA was issued a 100-day challenge from community groups following the ORD-Office of Environmental Justice (OEJ) Symposium, Strengthening Environmental Justice Research and Decision Making: A Symposium on the Science of Disproportionate Environmental Health Impacts. This challenge calls for a holistic research program with community involvement.

The existing components of the HHRP that are relevant to the new theme are LTG 3–Susceptible and Vulnerable Populations and LTG 4–Accountability. Some of the questions addressed by this research are: How and why are children differentially exposed to pollutants? What are long-term consequences of *in utero* exposures/stress? Are aging populations at higher risk? What metrics and indicators are needed to evaluate and remediate communities at risk? and How do we measure success (i.e., effectiveness of risk management decisions)?

The BOSC praised HHRP's Children's Health Program in the review and ORD is continuing its commitment to children's health. Six new full centers and six formative centers were funded in 2010 under the Children's Environmental Health and Disease Prevention Centers Program with NIEHS. The centers' work includes participatory research with involvement of community partners. Two workshops planned for fall 2010 will identify data gaps and research needs to help guide future ORD research planning. These workshops include the ORD-Regional Science Workshop on children's health and risk assessment, and the ORD-NIEHS-OCHP workshop Children's Health for a Lifetime: Where Research Meets Clinical Practice and Policy (with ATSDR-Superfund Pediatric Environmental Health Specialty Units).

ORD will continue to support the NCS Interagency Coordinating Committee and Workgroup and development of methods and sampling strategies for the NCS. In addition, ORD will continue its research to identify and evaluate potential sources of polychlorinated biphenyls (PCBs) in schools to better understand exposures to children, teachers, and other school workers, and to improve risk management decisions. EPA will investigate PCB-contaminated caulk, as well as other potential sources of PCBs in schools. Future research areas include exposures in very young children and in child care settings as well as school building practices and child/teacher performance.

ORD's responses to the specific recommendations of the BOSC are summarized below.

BOSC Recommendation: The program should conduct more translational research to link advances in fundamental exposure and toxicology science (LTGs 1 and 2) with environmental public health applications (LTGs 3 and 4).

ORD Response: The program is working to implement this recommendation. Some of the actions include:

- ✧ STAR grants and intramural "accountability" studies (LTG 4) are providing information on public health indicators.
- ✧ The Community-Focused Exposure & Risk Tool (C-FERST), an innovative Web-based tool with Google map interfaces, is being developed in collaboration with regional/community projects (LTG 2).
- ✧ An "Environmental Quality Index" is being developed (LTG 4).
- ✧ The STAR RFA "Understanding the Role of Nonchemical Stressors and Developing Analytic Methods for Cumulative Risk Assessment" was issued in 2009.
- ✧ The STAR RFA "Exploring Linkages between Health Outcomes and Environmental Hazards, Exposures, and Interventions for Public Health Tracking and Risk Management" was issued in 2009.
- ✧ The second STAR Tribal Grants Program RFA is planned for 2011.
- ✧ The program is considering a STAR RFA on school environments and performance (with the Department of Education).
- ✧ The program is considering a STAR RFA on Centers of Excellence on Environmental Justice (modeled after the Children's Environmental Health Research Centers) to include community-based participatory research.

BOSC Recommendation: Redress program imbalance within the life-stage arm of LTG 3 such that the strengths of the childhood susceptibility research thrust are matched with an expanded research program addressing the elderly as well as potential subgroups across the entire age range.

ORD Response: The HHRP is using available resources to: (1) evaluate response of different aged rats to air pollutants with the goal of informing PBBK models, (2) compare the responses of younger versus older asthmatics to air pollution, and (3) use an animal model to explore early *in-utero* exposures and long-term consequences on chronic diseases later in life, such as hypertension, diabetes, and metabolic syndrome. In 2009, ORD co-sponsored "Contribution of Environmental Stressors to the Developmental Origins of Health and Disease," with NIEHS, ATSDR, the Centers for Disease Control and Prevention (CDC), and the National Institute of Child Health and Human Development (NICHD).

BOSC Recommendation: Rethink the approach to asthma (LTG 3) as a target condition so that it is not simply approached as a surrogate of childhood susceptibility to new disease onset, but rather considered across the entire age range and in terms of pre-existing disease.

ORD Response: ORD will hold a workshop on asthma in fall 2010 that is focused on both community health and climate change. The program also is conducting controlled exposure studies on older asthmatics exposed to inhaled particles with both respiratory and cardiovascular outcomes to understand whether older asthmatics are at increased risk to endothelial injury and accelerated coagulation. In addition, the HHRP is examining the role of severity of asthma disease in conferring susceptibility to pollutants. This research will link to the new SPSW (whether toxicity pathways studied via gene expression and microRNA profiles are perturbed by pollutants in different ways in individuals with different asthma severity). The Children's Centers will address fundamental questions about the interactions among biological allergens and ozone in the etiology and progression of asthma, and about how asthma symptoms may be controlled by dietary intervention.

BOSC Recommendation: Incorporate additional case studies into LTG 4 and attempt to extrapolate from existing case studies to other examples.

ORD Response: Case studies are underway with the Agency's "Community Action for a Renewed Environment" (CARE) and "EJ Showcase Communities" programs. The results from two intramural "accountability" projects are being extrapolated to other examples: (1) salivary antibodies to water-borne pathogens are being evaluated for use in "Beaches" studies for OW, and (2) air pollution models that integrate and predict impacts of national and local (voluntary) actions, developed in New Haven, Connecticut (collaborative effort with Region 1), are being extrapolated to Bridgeport, Connecticut, a "Showcase Community." Additional case studies are expected from the new series of STAR grants on public health indicators, the new Children's Centers funded in 2010, and the new RFA for Tribal grants planned for 2011.

BOSC Recommendation: Restructure the HHRP for better linkages with other agencies.

ORD Response: The HHRP is being restructured; some components of the current program will go to the new SPSW Program and some will remain in the revised HHRP. The new theme for the HHRP is healthy people in sustainable communities. There will be increased focus on building strong state and tribal partnerships.

Dr. Darney closed her presentation with several "take home" messages. The HHRP has a long history as a "core" program that has benefitted multiple ORD and EPA partners. The 2009 BOSC review influenced new directions for the HHRP and ORD. Integrated transdisciplinary programs in ORD will provide new tools for solving 21st century environmental health problems, such as:

- ✧ Reducing risks of chemicals by identifying key events along toxicity pathways (existing chemicals) and designing safe new chemicals.
- ✧ Using advanced exposure and PBPK models to link exposures to health outcomes, interpret biomonitoring data, and inform risk mitigation.
- ✧ Protecting children and other vulnerable populations by considering their unique exposures and susceptibilities.
- ✧ Enabling communities, states, and tribes to participate in research to identify multiple stressors, reduce harmful exposures, and improve their environments to create sustainable well being.

The research portfolios will include complementary intramural and extramural efforts, and investments will be made to address the Administrator's priorities.

Dr. Sayler thanked Dr. Darney for her presentation and then asked about the definition of sustainable communities. Dr. Darney responded that sustainability means maintaining a balance between our consumption of natural resources and our use of ecosystem services so that we can maintain well being and growth without the negative impacts that ultimately will lead to our demise. She noted that EPA cannot accomplish sustainability on its own. It has to be defined on a basic level so that everyone can get involved. The Agency needs to look for starting points in community-based projects and work with partners to flesh out a program. Dr. Darney said that ORD would like to get the BOSC's input on the SPSW in October, so the subject of sustainability can be discussed more at that meeting.

Dr. Olden complimented the program's efforts to focus on sustainable communities. He mentioned that Dr. Darney's definition of a sustainable community meshes with that used at the City University of New York. He also was impressed with the new agenda for the revised HHRP.

Dr. Tharakan asked if ORD is investing any effort in the development of a checklist or criteria to measure whether a community is moving toward sustainability. Dr. Darney replied that Ric Linthurst, the NPD for the Ecosystem Services Program, is working on this issue for ecosystem services and it is expected that similar efforts will be done for the health program in the future.

ORD Update—Potential Relationships Between Hydraulic Fracturing and Drinking Water Resources

Dr. Kevin Teichman, Deputy Assistant Administrator for Science, ORD, EPA

Dr. Teichman said that his presentation would focus specifically on updating the BOSC on ORD's efforts on hydraulic fracturing and drinking water. He mentioned that if there were follow-up questions concerning Dr. Anastas' earlier remarks, he and Mr. Kadeli would try to respond to those questions.

The FY 2010 Congressional Appropriations Conference Report urged "EPA to carry out a study on the relationship between hydraulic fracturing and drinking water, using a credible approach that relies on the best available science, as well as independent sources of information. The conferees expect the study to be conducted through a transparent, peer-reviewed process that will ensure the validity and accuracy of the data. The Agency shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies in carrying out the study, which should be prepared in accordance with the Agency's quality assurance principles."

Dr. Teichman presented a diagram of the hydraulic fracturing lifecycle. A well is installed at the site; these wells are much deeper than in the past and a recent development is for the well to turn horizontal once it reaches the shale. A mixture of water, sand, and chemical agents is pumped into the well. The shale is fractured by the pressure of the fluids inside the well and fissures form in the shale around the well. Sand keeps the fissures open and natural gas flows from the fissures into the well. Water, hydraulic fracturing fluid, and water from the subsurface, which may be contaminated with other things such as arsenic, are pumped to the surface.

The FY 2010 budget allows EPA to spend $1.9 million on this effort. Another $2.5 million will be added in 2011. This limited budget would not fund a single hydraulic fracturing demonstration. Therefore, EPA must work with industry to move forward with the study. The Agency must be careful to avoid working too closely with industry, however, so that EPA is not accused of favoring industry. ORD wants to involve stakeholders in the study design and hear from people who think their homes have been affected by hydraulic fracturing sites. People from the local communities and local authorities as well as tribal representatives will be involved in study design so that the results will be more usable to them and the study's credibility will be evident.

The steps in the study design are as follows: (1) define the scope of the study; (2) identify key research questions; (3) evaluate background information, literature, and data relevant to the research questions to identify research and information needs; (4) develop an initial framework for the study and criteria for prioritization; (5) prioritize the research and develop an initial study design; (6) engage stakeholders to inform study design; (7) peer review initial study design and revise as needed; (8) implement the study; (9) monitor and report progress; (10) develop research products; and (11) peer review the research products.

The potential elements of the study include collection of background data and information, chemical characterization, potential field studies, modeling, and technology assessment. Dr. Teichman noted that because of competition among the various companies that do hydraulic fracturing, some companies consider the chemical characterization of the hydraulic fracturing fluid to be confidential; however, most in the industry think the information should be shared. Because of the differences across the country, EPA would like to do multiple field studies, which will require a collaboration of stakeholders.

In April 2010, EPA asked the SAB to provide input on the scope of the study, the research questions, the process to be used for prioritizing research, and the process used for obtaining balanced input from stakeholders. Representatives from other federal agencies, state and local governments, NGOs and associations, industry, trade associations, and private citizens participated in the SAB meeting that was held April 7-8, 2010. Sixty-four written comments and 15 oral comments were received at that meeting.

The final report from the SAB was released on June 24, 2010, and the primary recommendation was to focus on drinking water resources while recognizing hydraulic fracturing in a larger life cycle.

EPA will engage stakeholders (including individual citizens, communities, state and federal partners, industry, trade associations, tribes, and environmental organizations) in a variety of ways to exchange information and provide progress updates as the Agency plans, implements, and completes this study. Stakeholder involvement includes:

- ✧ Facilitated public meetings (Summer 2010): EPA Regions 2, 3, 6, and 8
- ✧ Sector-specific meetings (Summer 2010): federal agencies, states, NGOs, and industry
- ✧ Technical workshops (Fall 2010)
- ✧ Web-based outreach
- ✧ Peer review panel meetings, including requests for input via *Federal Register* notice
- ✧ Public comment during meetings and written comments
- ✧ State and federal partner consultations.

The timeline for the project indicated that meetings with state and federal partners would be conducted in late May/early June 2010, the Website would be posted in June, and public meetings would be held in July and August. The draft study design will be completed in September, technical workshops will be conducted in September and October, and peer review will be initiated in October. The study is expected to begin in January 2011, and initial study results are expected to be published by late 2012.

Dr. Sayler asked if there were any questions for Dr. Teichman. Dr. Demerjian said he was very concerned that the air side of this issue is not being addressed. Very little has been done on this topic. In addition, there are some concerns about fugitive emissions from lateral drilling. He mentioned that New York requires companies to provide information on the organic materials in the hydraulic fracturing fluids, which often contain benzene, xylene, and toluene. There are no data on the emissions from hydraulic fracturing processes. Is lateral drilling exacerbating greenhouse gas emissions? The Agency needs to look at these processes to ensure that they are safe and the emissions should be monitored. Dr. Teichman thought Dr. Demerjian made some important points. ORD is discussing with the Office of Air and Radiation (OAR) the possibility of supplementing ORD's funding so that the study can examine some of these air-related issues.

Ms. Zhuikov commented that this study will spark the interest of the public. She was pleased to see the SAB's recommendation on developing a communications plan but she did not see it in the study design process. What does ORD plan to do to communicate this study and its results? Dr. Teichman responded that OW will be assisting with these public meetings and communications. ORD is considering working with the Office of Public Affairs to develop materials that will inform the public about this study. In addition, the meetings will be professionally facilitated to ensure that the discussion remains on topic. He noted that it is important that the meetings do not become too bureaucratic or too technical. EPA wants the public to participate in the study and to conduct it in an open and transparent fashion. There will be efforts to communicate with the local communities and with the media.

Dr. Olden said he thought this was a case where the BOSC should make a strong statement to ORD about the government's need to review of the safety of the hydraulic fracturing process. He was surprised to learn that companies did not have to inform EPA about the composition of their hydraulic fracturing fluids. The Agency needs to make sure that hydraulic fracturing is not irreversibly contaminating our water sources.

Dr. Tharakan commented that this appears to be an engineering study at this point. What are the health agencies doing on this topic? Dr. Teichman replied that he has been in contact with NIEHS about the public meetings because ORD believes that the public will call for testing to be done. He pointed out that hydraulic fracturing fluids cannot be recovered in many cases so testing is important to assess their safety.

Dr. Hauchman said he attended the stakeholder meeting that was held in Dallas. The Agency received 100 comments, the meeting was attended by more than 600 people, and it lasted 4 hours. The people who benefit from the companies doing the hydraulic fracturing said they were not concerned about it and they supported the process. Others did not share their view, however, and it was clear that the public had little faith in the state oversight of these operations. Similar meetings will be held in Denver and New York. To address Dr. Demerjian's comment, Dr. Hauchman mentioned that Region 6 is doing a little work on air emissions associated with hydraulic fracturing, and ORD is supporting some work under the Regional Applied Research Effort (RARE) program. He noted that there was considerable concern about air emissions at the Texas meeting.

Dr. Sayler asked if the SAB report was available. Mr. Susanke responded that it was provided as background material and is in the meeting notebook. Dr. Sayler thought it would be helpful for the BOSC members to review that report before commenting further on this topic.

ORD Update—Gulf Oil Spill Update

Lek Kadeli, Deputy Assistant Administrator for Management, ORD, EPA

Mr. Kadeli stated that his comments would focus on ORD's efforts to support the response to the BP oil spill in the Gulf of Mexico. He explained that it had been 84 days since the explosion that killed 11 workers and the oil rig sank and the platform capsized. This is the worst environmental disaster to occur in United States' history and it has and will continue to have significant environmental and economic impacts. Eighty thousand square miles of fishing waters have been closed and many wildlife refuges have been threatened. There are many people in the Gulf working on mitigation and getting ready to start remediation efforts once the spill is finally contained. EPA has 165 workers from field offices, the EPA Regions, and headquarters who are dedicated to the response efforts and this number will grow as the activities move toward remediation.

Mr. Kadeli noted that Admiral Thad Allen is familiar with the work EPA did following Hurricane Katrina so he is aware of what the Agency can do to help. He thought the Admiral had done an outstanding job in leading the response efforts of the various federal agencies. This is a huge effort—770,000 barrels of oil have been recovered or flared over the past 80+ days, 600 vessels are assisting in the cleanup, and dozens of aircraft have been employed in the response. Remote vehicles are being used to do much of the work to plug the well because of the depth of the leak. Millions of feet of skimmers and booms are being used to contain the oil with varying degrees of success. There are concerns about the byproducts of the evaporated oil, the air emissions from flaring, and the effects of the dispersants. Mr. Kadeli stated that the monitoring data have not revealed any extraordinary air emissions. The data are available on EPA's Website. The data are subjected to quality assurance/quality control before they are posted, which usually occurs about 5-7 days following the sampling.

Although the use of dispersants in the Gulf response has been highly scrutinized, the dispersants are working as expected to break up the oil. Just 20 km from the site, the plumes are breaking up and the oil is droplet size. The EPA Administrator has been clear that if there is evidence that the negative impacts from the dispersants outweigh the benefits of their use, EPA will ensure that BP stops using the dispersants. It appears that the use of dispersants has been effective.

The Coast Guard directed BP to reduce the amount of dispersants used by 75 percent from the peak level. On May 26, EPA issued a directive to BP stating that dispersant spraying should be used as the last resort and subsea dispersant use should be limited to 15,000 gallons a day, which was much less than BP had

been using. BP can only use dispersants with rigorous monitoring; weather conditions, however, can be grounds for an exception. Monitoring is occurring all along the coastline and oxygen and toxicity levels are being tested. Both oxygen and toxicity have been at stable and viable levels.

In June, EPA did independent toxicity testing of eight different dispersants to determine if some were more toxic than others and if there were any concerns about endocrine disruption. The data of this independent testing were released on June 30. The tests indicated that Corexit is probably as good as any of the other dispersants tested with respect to toxicity.

EPA also has set up a Website to accept submissions on ideas for mitigating the oil spill. More than 20,000 suggestions have been submitted to the government; 2,000 to EPA alone. Some of the ideas were creative but not deemed to be useful at this time. A number of the ideas were forwarded to BP (the ones focused on the well head) and others were sent to the Coast Guard. There may be some demonstration projects conducted to evaluate the efficacy of some of the proposed ideas. The Coast Guard established a new Website about 3 weeks ago, which now serves as the one-stop-shop for suggestions to deal with the oil spill.

EPA is conducting monitoring in the Gulf and providing technical expertise on the best approaches to remediate the oil spill, particularly bioremediation. This approach is especially important for oil that has moved into marshland. Some companies want to use "super" microbes to deal with the oil and others want to optimize conditions to allow the indigenous microorganisms to clean up the oil. This latter approach appears to be the growing consensus. There are concerns about people trampling nesting areas during remediation efforts and doing more damage to the ecosystem. EPA will be receiving supplemental funding of $2 million to be used for engaging institutions along the Gulf in conducting research to look at the longer term impacts of the spill. This is a relatively small amount of funding but it likely will be part of a larger effort that will be initiated once the focus becomes restoration.

Dr. Sayler thanked Mr. Kadeli for his comments and asked if the BOSC members had any questions.

Dr. Philbert said that he found it bewildering that the taxpayers should have to pay for this testing. The testing should be funded with money set aside from the restitution funds. Mr. Kadeli responded that BP has committed to provide at least $50 million for research on the long-term effects of the spill; it is important for the Federal Government to be involved in this research. Dr. Philbert stated that he did not think BP should do that research. He then asked if BP had required response workers to sign a waiver concerning any health impacts associated with responding to the spill. Mr. Kadeli replied that he did not have information on any such waiver. He added that the exposure of workers and their health are of concern. The National Academies will be engaged to look at the exposure and health issues so that there is an independent group of experts making this assessment and reporting to the Federal Government.

Dr. Philbert noted that the use of surfactants has been substantially reduced, and most of the oil is staying in the subsurface where the water is cold. Is anything known about accumulation of oil and associated pollutants in benthic organisms and their effects on the food chain? Will EPA be examining this issue? Mr. Kadeli responded that both the oil and the dispersants are toxic, but the experts think it is less risky to use the dispersants. There is a tradeoff being made. With regard to the question about accumulation in benthic organisms, NOAA and the U.S. Fish and Wildlife Service are examining the implications to organisms in the water column. More work needs to be done before the effects are understood. For example, they are finding oil under the shells of blue crabs in the Gulf but it is not clear if this oil is coming through the crab's digestive system. In addition, it is not certain that the oil being detected is from the BP spill. More work needs to be done on bioavailability, especially with dispersant use, and the focus should be on the lower organisms in the food chain.

Dr. Demerjian asked if there was any monitoring along the shore for hydrocarbon species. Are they looking for semi-volatile organic compounds (SVOCs) that may have a role in aerosol formation? Is

there anyone trying to measure the flux of emissions from the surface plumes and the burden this is to the background hydrocarbon levels? Mr. Kadeli replied that there is sampling for VOCs but he was not certain about SVOCs. There is air sampling and testing all around the coastal area. He was not aware of any samples that exceeded the normal background levels of air toxics for the Gulf area. He noted that the background levels normally are high because of the significant presence of the oil industry. Dr. Demerjian encouraged the collection of data to measure the flux of the air emissions at the plumes. EPA and others will want these data when they are working on the modeling. Mr. Kadeli answered that there are aircraft doing monitoring with aerial imagery but less monitoring from the boats because of worker exposure concerns.

Dr. Haas commented that accidents are research opportunities. NSF has a mechanism in place to conduct research on little notice when these events occur. EPA does not have a similar mechanism that can be used to engage extramural researchers rapidly. Perhaps the Agency should consider setting aside some funding for such circumstances. Mr. Kadeli replied that EPA has had discussions with NSF about utilizing NSF's mechanism to do research. EPA could use that mechanism but it would be somewhat complicated. He added that EPA's research budget for oil-related issues had been only $500K to $700K per year for the last 5-6 years. Therefore, EPA has very limited resources available to address this issue and it would be very difficult to set much of this aside for accidents. In addition, the Agency is trying to address potential issues associated with biofuels and EPA does not even have enough funding to address those.

Public Comments

Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair

At 10:15 a.m., Dr. Sayler asked if anyone wished to make a public comment. No comments were offered. Mr. Susanke confirmed that no one had contacted him by e-mail or telephone to request time for public comment.

BOSC and SAB Liaison Update

Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair

Dr. Sayler stated that in the past there has been an SAB member who served as the liaison to the BOSC. There currently is no liaison; Dr. John Giesy, a former member of the BOSC Executive Committee, has volunteered to serve as the liaison to the BOSC but that has not been approved yet by Dr. Vanessa Vu.

The SAB has invited the BOSC to participate in any activity that may be of interest. The only stipulation is that the BOSC member who attends the SAB activity must report back to the Executive Committee on what transpired.

Dr. Hauchman said that Mr. Susanke will follow up with Dr. Vu to get a status report on the appointment of a new liaison. Dr. Sayler said that, in the absence of a new liaison, he had been trying to keep the SAB informed of the activities of the BOSC. The work of the Decision Analysis Workgroup has dovetailed nicely with the efforts of the SAB on decision making. The SAB had interviewed the regional and headquarters staff about decision making, and Dr. Sayler participated in an SAB meeting at which this was a central topic. He alerted the SAB about the BOSC Workgroup's efforts and informed them of the report from that Workgroup. He agreed to share that report with the SAB. Mr. Susanke prepared a synopsis of the salient features of the report and informed the SAB that it fits well with its recent hydraulic fracturing report. The SAB decided to reference the BOSC's decision analysis report in the hydraulic fracturing report and suggested that EPA consider decision analysis techniques in establishing research priorities.

Dr. Sayler mentioned that he also serves on the SAB's Committee on Science Integration for Decision Making, which is preparing a report. He noted that Drs. Ryan and Haas also serve on the SAB, and can share information on their SAB involvement. He asked the Executive Committee members to notify him and Mr. Susanke if they are interested in participating in an SAB activity. Dr. Sayler mentioned that the mission of the BOSC is different from that of the SAB, but there are some activities that are of mutual interest.

Future Business/Open Forum

Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair

Dr. Sayler informed the BOSC members that the next Executive Committee meeting would be held in Washington, DC, probably in early to mid-October. After some discussion, it was decided that October 18-19, 2010, would be the best dates for the next meeting.

There is a program review of the Land Research Program coming up. Dr. Ryan has agreed to chair that Subcommittee, and Dr. Sayler thought it would be good experience for one of the new Executive Committee members to serve as the co-chair for that Subcommittee. The BOSC needs to prepare a short response to the mid-cycle progress reports from the SP2 and HHRA Research Programs. Dr. Sayler suggested discussing these responses on a conference call in late August.

Dr. Sayler indicated that the BOSC wants to continue its discussion of informatics and data mining at the October meeting in Washington, DC. He asked Drs. Philbert and Haas to work with him to identify some knowledgeable presenters for the October meeting. Mr. Susanke suggested tailoring the presentations toward ORD's needs. Dr. Haas suggested that knowledge repositories be a topic for the Washington meeting. Dr. Sayler said he was looking at what the Department of Energy has been doing to use technology to integrate information across many different scales. He thought it might be helpful to bring several different experts to the October meeting to discuss these various activities. Dr. Philbert stated that another area to address is how to use old data with new frameworks—cross-platform continuity and compatibility. Dr. Sayler mentioned that bibliometric analysis is another topic for the October meeting. The BOSC has struggled with how to discriminate between intramural and extramural researchers; he noted that the National Research Council (NRC) report suggested that the program be considered as a whole—not divided between intramural and extramural. There have been arguments, however, to support both opinions.

Dr. Sayler mentioned that another issue to consider is how ORD makes its scientific capabilities available to the regions. An upcoming SAB report will reflect the regions' view that ORD is not providing the support that they need.

Dr. Haas said that the Drinking Water Subcommittee probably will not have a draft report ready for the October meeting. The face-to-face review meeting will likely take place in September or October.

Dr. Hauchman asked the Executive Committee members to share their views on how the BOSC could assist with ORD's technical support issue. Historically, the BOSC has not dealt with the issue of technical support and the loop back to inform research. There is value in conducting a needs assessment and dealing with the tension between the need for technical support and the research that the ORD staff wants to do. ORD plans to hire a contractor to do an analysis of this issue. Dr. Hauchman noted that ORD would welcome the BOSC's input on this task.

Dr. Sayler asked that the BOSC be allowed to provide input early in this effort. He pointed out that it falls within the Board's purview and comes up at every program review. Dr. Demerjian commented that it is one of the charge questions and most subcommittees have found it difficult to answer. Dr. Hauchman stated that the BOSC will hear more about this in the review of the Land Research Program.

Referring back to the issue of bibliometrics, Dr. Philbert stated that the NCER Standing Subcommittee pointed out in its last report that academic bibliometrics—impact factors and immediacy indices—are not that helpful to ORD. It is more important for ORD to determine how the research outputs have impacted public health through regulations, policies, guidance, and similar means. Dr. Haas commented that the BOSC has been conditioned to look at outcomes rather than outputs. The NRC report noted that outcomes are very difficult to measure; therefore, ORD needs to look for early markers of outcomes that predict the outcome is likely. Dr. Cozzens mentioned that the term used in that report for these early markers was "intermediate outcomes," and that concept is now widely accepted.

Dr. Sayler said that there will be plenty of topics for discussion on the August teleconference and at the October meeting. Mr. Susanke thought it might be necessary to postpone some of the topics to a future meeting. Dr. Sayler asked if it would be possible to postpone the presentation on the SPSW Program, and Mr. Susanke replied that the program has made a lot of progress and would like the BOSC to consider forming a standing subcommittee to provide ongoing advice. It may take 6 months to form the subcommittee so it would be best not to postpone that presentation. Drs. Philbert and von Stackelberg indicated that they would like to serve on that subcommittee. Mr. Susanke said that he would be working on forming a subcommittee. Dr. Sayler asked if the ORD response to the decision analysis report would be ready for the October meeting, and Mr. Susanke indicated that ORD will try to have a response ready.

Dr. Hauchman indicated that he had to leave soon but he wanted to thank the BOSC members for their time and input. Referring to Dr. Olden's early comment about the importance of ORD responding to the BOSC's recommendations, he emphasized that ORD values the input and he has been impressed with how many changes have been implemented by programs as a result of the BOSC reviews.

Dr. Sayler said that he was a guest observer on the Nanomaterial Case Study review. He noted that this was a perfect opportunity for the decision analysis pilot.

BOSC Decision Analysis Workgroup—Review of ORD Nanomaterial Case Study Workshop: Methods and Procedures to Identify and Prioritize Research Needs

Dr. Mike Davis, Senior Science Advisor, NCEA, ORD, EPA

Dr. Davis explained that ORD wanted to identify nanomaterial research needs and directions and refine a strategic approach for establishing priorities. They took a bottom-up approach, looking at specific applications. The case studies are not an end in themselves, but a starting point for a collective judgment process. The case studies were used to identify questions that would need to be addressed if they were doing a Comprehensive Environmental Assessment (CEA). The case studies are not completed risk assessments but are structured around a CEA approach, which combines a product life cycle framework with the risk assessment paradigm. The CEA approach considers primary and secondary contaminants, multiple environmental media, fate and transport processes, cumulative and aggregate exposure, and ecological as well as human health risks across the life cycle of a product. The features of the CEA framework approach include:

- ✧ Holistic and systematic, not just a checklist
- ✧ Qualitative and quantitative
- ✧ Primary and secondary substances
- ✧ Single, cumulative, and aggregate exposure
- ✧ Direct and indirect impacts
- ✧ Comparative—alternative choices and risks vs. benefits.

This approach provides guidance to risk managers (highlighting tradeoffs, focus on monitoring and mitigation, and adaptive management). In addition, the CEA framework approach can be used to identify information gaps and priorities. Dr. Davis mentioned that there is confusion about life cycle assessment (LCA) and CEA. He noted that CEA is more qualitative than LCA. CEA, as a process, uses collective judgment and involves diverse perspectives (multidisciplinary, multi-stakeholder). It also involves a substantial number of participants, avoids arbitrary boundaries, and is iterative.

The key questions for the nanomaterial case studies were: What do we know? and What do we need to know to be able to do a CEA of nanomaterials? Nanoscale titanium dioxide (nano-TiO_2) and nanoscale silver (nano-Ag) were selected for the case studies. Case Study #1 focused on nano-TiO_2 for water treatment, Case Study #2 focused on nano-TiO_2 in sunscreen lotion, and Case Study #3 focused on nano-Ag in disinfectant spray.

The EPA Nanomaterial Case Study Workshop was held September 29-30, 2009, in Research Triangle Park, North Carolina. Diverse technical and stakeholder perspectives were represented. Fifty participants were invited and they were balanced across sectors (academia, government, industry, NGOs, and other) and disciplines (technical, scientific, policy, and other). There was a pre-workshop review and ranking of research/information needs. Nominal Group Technique (NGT) was used to rank priority research needs. Participants identified and prioritized research needs for: (1) specific applications of nano-TiO_2, (2) nano-TiO_2 regardless of application, and (3) nanomaterials in addition to nano-TiO_2.

NGT is a method that enables a set of persons to identify and rank choices. NGT's typical features include: (1) each individual is allowed the same amount of time to state his/her highest priorities, (2) the number of participants is up to ~25 per group, (3) facilitators guide consolidation of similar or related priorities, and (4) there is multi-voting for the 10 highest priorities. For the EPA workshop there were two NGT groups, each with 25 members. The two NGT groups' priorities were consolidated, and breakout groups (5 members per group) prepared narratives on the top priorities.

The top-ranked issues using NGT were:

- ✧ Approaches and methods for evaluating the ecological and human effects of nano-TiO_2.
- ✧ Physicochemical characterization of nano-TiO_2 throughout the life cycle stages, environmental pathways, and fate and transport.
- ✧ Analytical method evaluation, development, and validation for analysis of nano-TiO_2 in relevant matrices.
- ✧ Nano-TiO_2 product-focused physicochemical characterization; changes and possible effects through the life cycle.
- ✧ Exposure pathways and life cycle stages.
- ✧ Spatial and temporal distribution and magnitude of anthropogenic and non-anthropogenic nano-TiO_2 in the environment.
- ✧ Using mechanism of action (MOA) information to drive toxicity testing.
- ✧ Long-term effects.

Dr. Davis mentioned that there were 8 rather than 10 issues that floated to the top in the NGT process. He noted that these issues are not presented in any rank order. Three prominent themes were identified:

- ✧ Physicochemical characterization
  - Identify key properties
  - Develop/apply methods

- Relate to life cycle stages, fate and transport, matrices, exposure, effects

✧ Effects characterization (ecotoxicity, human health)

- Standardize/harmonize test protocols for acute, subacute, and chronic studies
- Reference materials
- Mechanisms

✧ Exposure characterization

- Sources/life cycle stages, pathways, routes
- Typical and atypical (high-end)
- Environmental spatial/temporal distribution, background levels, natural vs. anthropogenic, bioaccumulation.

Dr. Davis closed his presentation with some of the lessons learned from the 2009 workshop. The questions and research needs should have been refined and one, smaller NGT group of 25 to 30 members should have been used. More formal "argument" should have been encouraged and there should have been less consolidation of issues. In addition, mid-level priorities should have received more focus and additional time should have been allocated to the breakout group session.

Dr. von Stackelberg explained that the BOSC Decision Analysis Workgroup was asked to review the Nanomaterial Workshop Report and comment on the process that was used to identify priority research needs. She reminded the Executive Committee members that nearly 2 years ago, ORD indicated that it was interested in using VOI or a similar decision analytic approach to help in identifying research needs and priorities. The BOSC formed a workgroup to discuss this topic and, in conjunction with the National Risk Management Research Laboratory (NRMRL), convened a workshop to discuss the topic. The workshop included representatives from other federal agencies and academia as well as private consultants. The report prepared by the workgroup following that workshop included nanomaterials as one of the case studies.

Dr. von Stackelberg indicated that the workgroup was asked to review the process that is described in the Nanomaterial Case Study Report rather than the outcomes (the priorities identified). She noted that decision analysis approaches are used to make the decision-making process more transparent and to arrive at better decisions; however, it is not always easy to implement these approaches.

Dr. von Stackelberg stated that NGT may have worked for ORD in this case study and the group may have arrived at the desired outcomes (a list of priority research needs); however, NGT, as a process, falls short of the BOSC Workgroup's expectations to quantitatively, rigorously assess how research is allocated and the tradeoffs being made by funding project "x" rather than project "y." There is a lot that is not addressed by NGT. In the mid-1980s, there were numerous exercises to link NGT with more formal decision analysis methods. Our understanding of optimization in the mathematical sense has increased dramatically since 2005, so now there are many tools available for formal decision analysis, but analysts often do not know how to use them.

Dr. von Stackelberg said that she recently attended a meeting on the SPSW Program where the attendees talked about employing some formal decision analysis method that goes beyond NGT. She mentioned that although the nanomaterials case study was used at the decision analysis workshop, not much was done with it because of the different opinions within those attending the workshop. She added that research on nano-TiO_2 as a sunscreen agent will be different from research on nano-TiO_2 for water treatment. The case studies help EPA figure out the important questions that need to be addressed.

If ORD's ultimate goal is to develop a broad long-range strategy for formal decision analysis, then perhaps ORD should convene a workshop on comprehensive evaluation frameworks to develop a decision tree, which indicates that "x" has to be done before "y" can be started. This may be a better

approach than using the case studies. The NGT process helped ORD prioritize the research questions/issues but it did not identify what research needs to be done or what ORD needs to get from that research. Dr. von Stackelberg said she had trouble transferring the ranked questions into research priorities.

Dr. Sayler asked Dr. von Stackelberg to submit her comments on the Nanomaterial Case Study Workshop Report in writing. Dr. von Stackelberg replied that she had prepared a formal response to distribute to the Executive Committee for comment.

Dr. Philbert said that it is important to remember that "perfect is frequently the enemy of good." The report was exactly what he would expect to achieve from the process. The group identified the top eight issues that EPA should address for these case studies. The process worked and it resulted in valuable information. Now, ORD should consider doing a second workshop to identify the research that needs to be done to address these priority needs. Dr. von Stackelberg agreed that the workshop was a great first step, but she thought ORD could go further. Dr. Haas thought it was a good brainstorming session to identify a list of priority needs. Now, ORD needs to determine what tasks need to be done, how much those tasks will cost, and how each task helps answer the underlying questions. That will move ORD beyond the NGT process and toward finding the answers it is seeking.

Dr. von Stackelberg agreed to send her draft response to the workshop report. Dr. Sayler stresssed the need to specifically mention the prioritized research needs. Dr. Philbert said he could provide comments on the list of priorities developed at the workshop. Dr. von Stackelberg did not think the BOSC was supposed to comment on the priorities, just the process. Mr. Susanke said that the BOSC needs to comment on the workshop priorities which are in essence the workshop recommendations. Does the BOSC agree that these are the top priorities? Dr. Philbert replied that he would have no difficulty providing such input.

Dr. Demerjian asked if water treatment and sunscreen lotion were the two major uses of nano-TiO_2 or if there were many other uses. Dr. Davis responded that the majority of nano-TiO_2 is not going into these two uses, but it is difficult to obtain information on all the different applications. It was difficult to find information on its use in water treatment and it turns out that nano-TiO_2 is not being used in this application. Dr. Philbert thought these two applications were appropriate in that they impact the environment and data are available. Dr. Davis mentioned that ORD wants to use this approach with coating materials and extend it to carbon nanotubes.

Dr. Cozzens said that she would have expected to see much more input from worker organizations and consumers at the workshop; however, it does not appear that these folks were invited to participate. Dr. Davis responded that they tried to include that input through representatives of labor unions and consumers unions, as well as worker safety representatives. Dr. Sayler commented that the workshop included a very diverse group and ORD made a concerted effort to ensure reasonable stakeholder representation. Dr. Davis added that they tried to get NGOs involved as well. Dr. Cozzens stressed that the groups to be affected need to be involved in the process. Dr. Philbert pointed out that Appendix E of the report identifies the workshop participants. There are a number of individuals from consumer protection groups as well as representatives from NIH and FDA. It may not be a complete list but it is very good from EPA's perspective.

Dr. Sayler thought the response from the BOSC should identify any weaknesses of the process and make suggestions for improving it. Dr. Tharakan asked if ORD is seeking the BOSC's approval of the process. Dr. Sayler replied that the BOSC is acknowledging that a verified process was used at the workshop and that it yielded bona fide results. Dr. Tharakan then asked if the report will identify the weaknesses of the process as well. Dr. Sayler confirmed that it would. Dr. Cozzens asked about the baseline. Dr. von Stackelberg responded that the baseline would be a group of people coming together and making a

decision using no process. She noted that with NGT it is important to ensure that there are no dominant voices.

Dr. Sayler asked Drs. von Stackelberg and Philbert to communicate and move the response forward within the next few days. Dr. Philbert asked the Executive Committee members to e-mail their comments on the workshop report to him so that he can incorporate them into a draft BOSC EC response.

Dr. Sayler explained that there would be an informal discussion with representatives of GAO immediately following the BOSC meeting. In addition, the afternoon would include a field study tour. He thanked the members for their participation and adjourned the Executive Committee meeting at 12:20 p.m.

Action Items

- ✧ Mr. Susanke will follow up with Dr. Vanessa Vu about the status of appointing a new liaison from the SAB to the BOSC. Specifically, he will determine if a decision has been made about Dr. John Giesy serving as the liaison.

- ✧ Executive Committee members will notify Mr. Susanke and Dr. Sayler if they would like to participant in any of the upcoming SAB activities.

- ✧ Dr. Sayler will work with Drs. Philbert and Haas to identify knowledgeable presenters on informatics and data mining for the October meeting in Washington, DC.

- ✧ Dr. Ryan will draft a response from the BOSC—a short summary of the Executive Committee's comments—on the mid-cycle progress report for the SP2 Research Program.

- ✧ Dr. Sayler will draft a response from the BOSC – a short summary of the Executive Committee's comments – on the mid-cycle progress report for the HHRA Research Program.

- ✧ Dr. von Stackelberg will send her draft response on the Nanomaterial Case Study Workshop Report to Dr. Philbert and Mr. Susanke by July 16, 2010. Mr. Susanke will distribute the draft response to the Executive Committee for review and comment.

- ✧ Mr. Susanke will schedule a conference call in late August to discuss and approve the BOSC responses to: 1) the mid-cycle progress report for the SP2 Research Program; 2) the mid-cycle progress report for the HHRA Research Program; and, 3) the nanomaterial workshop summary.

- ✧ Mr. Susanke will distribute materials to the Executive Committee to be discussed on the August conference call.

All materials that were transmitted during and for this meeting are in the public meeting binder in the BOSC central files in Washington, DC.

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44th EXECUTIVE COMMITTEE FACE-TO-FACE MEETING
AGENDA
July 12 - 13, 2010

Office of Research and Development
National Health and Environmental Effects Laboratory
Western Ecology Division
200 SW 35th Street,
Corvallis, Oregon 97333

Monday, July 12, 2010

8:30 a.m. – 9:00 a.m.	Registration	
9:00 a.m. – 9:20 a.m.	Welcome and Introductions - Review of April Meeting Minutes - Overview of Agenda	Dr. Gary S. Sayler, Chair, Executive Committee
9:20 a.m. – 9:30 a.m.	BOSC DFO Remarks - Administrative Issues	Mr. Greg Susanke, Designated Federal Officer (DFO), Office of Research and Development (ORD)
9:30 a.m. – 9:45 a.m.	Overview of ORD Chemical Research Realignment: Safe Products for a Sustainable World	Dr. Bob Kavlock, Director National Center for Computational Toxicology, ORD
9:45 a.m. – 10:45 p.m.	Mid-Cycle Progress Report - Human Health Risk Assessment	Dr. Stan Barone, National Program Director, Research Program, ORD
10:45 a.m. – 11:00 a.m.	Break	
11:00 a.m. – 12:00 noon	Mid-Cycle Progress Report - Safe Pesticides/Safe Products Research Program	Dr. Elaine Francis, National Program Director, ORD
12:00 noon – 1:00 p.m.	Lunch	

1:00 p.m. – 3:00 p.m.	Ecosystem Informatics Session - Overview Ecosystem Informatics Program	Dr. Julia Jones, Director Oregon State University (OSU)
	- Computer Science Approaches to Species Modeling	Dr. Tom Dietterich, OSU
	- Mathematics of Ecological Dispersion	Dr. Ed Waymire, OSU and Dr. Enrique Thomann, OSU
	- Questions and Discussion	
3:00 p.m. – 5:00 p.m.	Lab Tour: Western Ecology Division, National Health and Environmental Research Laboratory, ORD	
5:00 p.m.	Recess	

Tuesday, July 13, 2010

8:30 a.m. – 9:15 a.m.	ORD Response to BOSC Human Health Report	Dr. Sally Perrault Darney, National Program Director for Human Health, ORD
9:15 a.m. – 10:00 a.m.	ORD Update	Dr. Kevin Teichman, Deputy Assistant Administrator for Science, ORD
10:00 a.m. – 10:15 a.m.	BOSC and SAB Liaison Update	Dr. Gary Sayler, Chair Executive Committee
10:15 a.m. – 10:30 p.m.	Public Comment	
10:30 a.m. – 10:45 a.m.	Break	
10:45 a.m. – 12:30 p.m.	BOSC Decision Analysis Workgroup - Review of ORD Nanomaterial Case Study Workshop: Methods and Procedures to Identify and Prioritize Research Needs	Dr. Katherine von Stackelberg, Workgroup Chair, Executive Committee Dr. Mike Davis, Senior Science Advisor, National Center for Environmental Assessment, ORD

12:30 p.m. – 1:00 p.m.	Future Business/Open Forum - Next EC Meeting - Future Work - Questions/Discussion	Dr. Gary Sayler, Chair, Executive Committee
1:00 p.m.	Adjourn	
1:00 p.m. – 1:30 p.m.	Lunch	
1:30 p.m. – 4:30 p.m.	Field Study Tour	